National Biosafety Framework for Guyana

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National Biosafety Framework for Guyana

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Environmental Protection Agency
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ABS	Access to Genetic Resources and Benefit-Sharing
APA	Amerindian Peoples Association
BCH	Biosafety Clearing House
CARDI	Caribbean Agricultural Research and Development Institute
CARICOM	Caribbean Community
CBD	Convention on Biological Diversity
COTED	Council for Trade and Economic Development of CARICOM
CPB	Cartagena Protocol on Biosafety
CSME	Caribbean Single Market and Economy
DDL	Demerara Distillers Limited
DPP	Director of Public Prosecution
DNA	Deoxyribonucleic acid
ELISA	Enzyme-Linked Immunosorbent Assay
EIA	Environmental Impact Assessment
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organisation
FPD	Food Policy Division, Ministry of Health
GA/FDD	Government Analyst/Food and Drugs Department, Ministry of Health
GBC	Guyana Biotechnology Corporation
GCCI	Georgetown Chamber of Commerce and Industry
GDF	Guyana Defence Force
GE	Genetically Engineered
GFC	Guyana Forestry Commission
GGMC	Guyana Geology and Mines Commission
GM	Genetically Modified
GMA	Guyana Manufacturing Association
GMC	Guyana Marketing Corporation
GMOs	Genetically Modified Organisms
GNBS	Guyana National Bureau of Standards
GoG	Government of Guyana
GRDB	Guyana Rice Development Board
GSA	Guyana School of Agriculture Corporation
GuySuCo	Guyana Sugar Corporation Inc.
GWI	Guyana Water Incorporated
HACCP	Hazard Analysis Critical Control Point
IAST	Institute of Applied Science and Technology
IDS	Institute of Development Studies
IICA	Inter-American Institute for Cooperation on Agriculture
IPPC	International Plant Protection Convention
IPR	Intellectual Property Rights
LMOs	Living Modified Organisms
NCERD	National Center for Educational Resource Development
MDG	Millennium Development Goals
MFCL	Ministry of Fisheries, Crops and Livestock
NARI	National Agricultural Research Institute
NBAP	National Biodiversity Action Plan
NBA	National Biosafety Authority
NBIU	National Biotechnology and Biosafety Inspection Unit

NBF	National Biosafety Framework
NCC	National Coordinating Committee
NCA	National Competent Authority
NEA	National Executing Agency
NEAP	National Environmental Action Plan
NDS	National Development Strategy
OAS	Organisation of American States
OECD	Organisation of Economic Cooperation and Development
PAHO/WHO	Pan American Health Organisation/World Health Organization
PRS	Poverty Reduction Strategy
PRSP	Poverty Reduction Strategy Paper
PSC	Private Sector Commission
SPS	Sanitary and Phytosanitary Measures of WTO
STI	Science, Technology and Innovation
THAG	Tourism and Hospitality Association of Guyana
UG	University of Guyana
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
UN	United Nations
WIPO	World Intellectual Property Rights Organization
WTO	World Trade Organisation

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1. GENERAL INTRODUCTION

Guyana became a signatory to the United Nations Convention on Biological Diversity (UNCBD) on August 29, 1994. Articles 8 (g) and (h) of the Convention outlines the duties of the parties to ensure that the necessary measures are taken to address Biosafety issues as a result of the use and applications of modern biotechnology.

In November 2002, the 16th Global Environment Facility (GEF) Council approved the UNEP-GEF Global Project on "Development of National Biosafety Frameworks" aimed at:

- Assisting up to 100 countries to prepare their National Biosafety Frameworks; and
- Promoting regional and sub-regional collaboration and exchange of experience on issues of relevance to the national biosafety frameworks.

Prior to the entry into force of the Cartagena Protocol on Biosafety on September 11, 2003, Guyana established a National Coordinating Committee on Biosafety as a sub-committee of the National Biodiversity Advisory Committee to advise and guide impending issues leading to the preparation of the National Biosafety Framework Development project document.

1.1 KEY STAKEHOLDERS IN THE PROCESS

The UNEP-GEF Project on the Development of the National Biosafety Framework of Guyana started in May, 2004 and ended in December, 2006. The following were the key stakeholders in the process:

- The National Executing Agency for the UNEP-GEF project was the Environmental Protection Agency of Guyana with Mr. Doorga Persaud as the Executive Director, who can be contacted at email: epa@epaguyana.org.
- The National Project Coordinator was Mr. John Cartey Caesar whose address is: John C. Caesar, Senior Lecturer, Department of Biology, Faculty of Natural Sciences, University of Guyana, Box 10-1110, Georgetown, Guyana; Email: jccaesar@yahoo.com; Telephone: 592 – 222 - 6004 or 222 - 6610; Fax: 592 – 222 - 6610.
- The National Coordination Committee consisted of 21 members, being representatives of key stakeholder institutions (Annex 1a) previously identified by the NEA with later inputs by the National Project Coordinator. The contact details of the membership of the NCC (Annex 1b) as well as those who succeeded the foundation members are provided below.

1.2 BRIEF INTRODUCTION TO GUYANA

1.2.1 Basic national information

The basic national information is well captured in the excerpt Box 1 from the National Development Strategy (NDS, 2000).

Box 1. Basic information on Guyana.

- Guyana, with an area of 83,000 square miles or 215,000 square kilometres, is located on the northern coast of South America, and is the only English-speaking country on that continent. It is bounded on the north by the Atlantic Ocean, on the east by Suriname, on the south and south-west by Brazil, and on the west and north-west by Venezuela.
- Guyana is physically divided into four types of landforms: (i) a flat coastal, clayey belt which is about 4.5 feet below sea level, and in which most of its agricultural activity occurs; (ii) a sand belt, to the south of the coastal belt, which includes the Intermediate Savannas; (iii) an undulating, central peneplain which comprises more than half of the country's area, and in which are located lush, almost pristine, tropical forests, and extensive mineral deposits. This landform stretches from the sand belt to the country's southern boundary and encompasses, also, the Rupununi Savannas which border Brazil; and (iv) the highlands which are to be found in the midwestern area. This portion of the Guiana Highlands includes the Pakaraima mountain range.
- Guyana has a plentitude of natural resources: fertile agricultural lands on the coastal plain and in the riverain areas; vast areas of tropical hardwood forests of various ecosystems and with a multitude of plant and animal species; abundant fish and shrimping grounds, both in its numerous rivers and in the Atlantic Ocean to its north; and a wide variety of minerals, including gold, diamonds, a range of semi-precious stones, bauxite and manganese. Moreover, because of its many rivers (the word "Guyana" means "land of many waters"), its potential for hydropower is immense.
- Guyana lies wholly in the tropics and possesses an equatorial climate that is characterised by seasonal rainfall, high humidity, and small variations in temperature. There are two rainy seasons which occur from May to June, and from November to January. The average daily temperature is about 80º F (26 ºC).
- The country has a multi-racial population which in 1999 was estimated to be about 745,000 [761,000 according to 2005 census report], or just over three persons per square kilometre. However, because about 90 percent of the country's population lives in the coastal zone which comprises only about 7.5 percent of its total land area, the actual living-space of most of the population is cramped.

(Source: National Development Strategy 2000, Government of Guyana.)

The issue of land use and legal and administrative oversight of such also influence the parameters for defining biodiversity and natural resource use, management, and related environmental implications in Guyana. It is within this contextual framework that the national development of Guyana, including the National Biosafety Framework and related harmonization of legal instruments, must be envisaged.

1.2.2 National biodiversity wealth

Guyana is considered a well-resourced country in terms of biodiversity, the inventory of which is far from complete (see Box 2). Within the Caribbean Community of nations, it ranks among the top three biodiversity rich countries – Belize, Guyana, and Suriname. On the basis of endemic species, it is definitely the richest in biodiversity wealth, although this is yet to be well articulated for universal authentication. Studies on biodiversity inventory are still on-going, however, based on this limited information, areas of biological interests have been identified for the country (Figure 1).

Box 2. Brief summary of the biodiversity wealth of Guyana.

The Guiana Shield covers an area of approximately 2.5 million square kilometres with a distinct floristic province consisting of over 8000 species of which approximately 50% are believed to be endemic to the Shield (Maguire, 1970). According to Berry *et al* (1995), 3763 plant species of 118 genera belonging to 4 families are endemic to Venezuelan Guayana (i.e. Venezuela part of the Guiana Shield) of which 61 endemic genera occur in Guyana. Among regional endemics found in Guyana are *Victoria amazonica*, *Arapaima gigas*, *Pteroneura brasiliensis*, and *Priodontes giganteus*. *Chlorocardium rodiei*, a prime timber species, has a range almost 98% restricted to Guyana. An estimated 20% of Guyana's 500 orchids are endemic to Guyana. Other notable endemic tree species are *Dicymbe alstoni*, *Vouacapoua macropetala*, and *Swartzia Ieiocalycina*, The Guiana Shield is a neotropical centre of endemism (Prance 1982, 1989). Guyana, with an area of 215,000 square kilometers, is one of five countries in the world with a very high percentage of forest cover and low human population pressure.

The extremely low population pressure in most of the forest belt has facilitated the occurrence of large expanses of pristine rainforest supporting over 6000 plant species; 1400 chordates; 834 arthropods; 426 fungi; 33 bacteria; 13 nematodes; 44 algae; 17 molluscs and an estimated 30 viruses. The 1400 plus chordates comprise 123 mammals; 711 birds; 102 reptiles; 77 amphibians; and 352 freshwater fish (GAHEF/UNEP 1992). Most of these biodiversity inventory figures have undergone upward revisions recently, with significant increases in the arthropod and fungal taxa.

(Source: www.biodiv.org/)

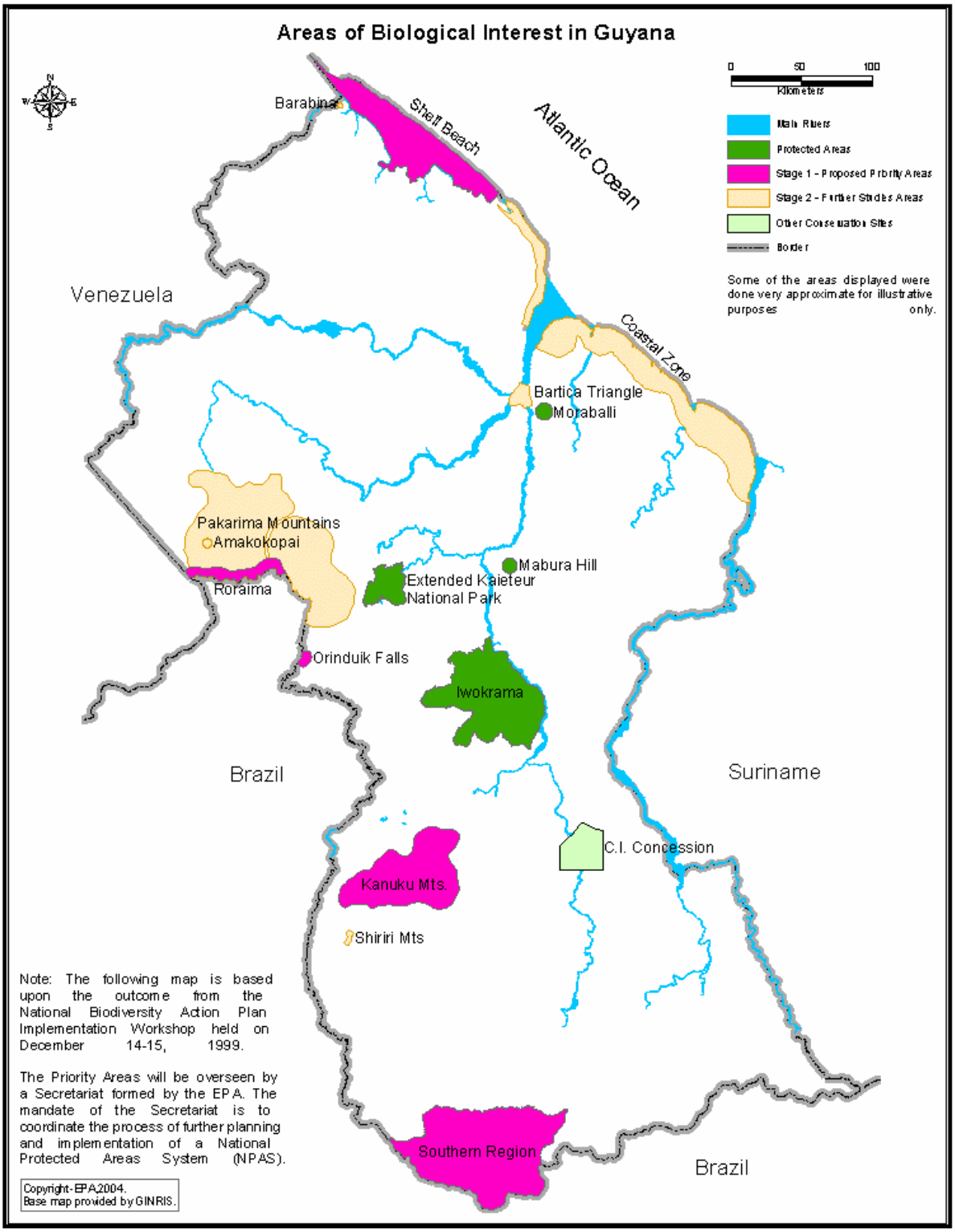

Figure 1. Map of Guyana showing areas of biological interest.

1.2.3 National development thrust

Guyana is part of the Guiana Shield[1] of north-eastern South America and is richly endowed with natural resources including fertile coastal and riverine agricultural lands, vast tropical hardwood forests of various ecosystems, rich biodiversity; abundant fish, and a wide variety of minerals, including gold, diamonds, a range of semi-precious stones, bauxite and manganese. However, it is Guyana's rich biodiversity heritage that makes the CBD important to Guyana. Guyana's commitment to the conservation and sustainable utilisation of biodiversity is embodied in two action plans: the National Biodiversity Action Plan (NBAP); and, the National Environmental Action Plan (NEAP). In recognition of the benefits of biotechnology coupled with the need for biosafety guidelines to protect the natural biological and cultural resources, Guyana implemented the National Biosafety Framework (NBF) Project. This present document is a component of the general framework provided for wise and safe use of the rich natural resources of Guyana for national development.

Guyana's economy is dependent on the production and export of its natural resources, with agriculture (sugar, rice, fishery, non-traditional crops), gold, diamond, timber and bauxite, accounting for most of the output of the productive sectors. The National Development Strategy (NDS) of Guyana indicates that Guyana is vulnerable to environmental pressures, which include fragile forest ecosystems; continuous threats to the narrow coastal belt from inundations from the Atlantic Ocean, rivers and inland water conservancies; dependence of the entire economy on coastal plantation type agriculture, and the exploitation of the country's forest wealth and minerals; and, poverty. Further, exploitation of natural resources for national development must take cognisance of these vulnerabilities. The role of biotechnology, biosafety and biosecurity to the use of the rich natural resources for national development assumes greater importance.

A look at the demography and distribution of current exploitable natural resources towards the national good shows severe pressure on the populated low coastal plains and comparatively greater opportunities in the sparsely populated hinterland or interior regions (Table 2).

[1] The Guiana Shield covers an area of 2.5 million km^2 and accounts for more than 25% of the world's remaining tropical rainforests with some 80-90% of it still in pristine condition. It contains an estimated 20,000 vascular plant species, 2,200 freshwater species, 975 bird species, 282 mammal species, 280 reptile species, and 272 species of amphibians. (Source: Conservation Priorities for the Guayana Shield, Conservation International, Washington. 99p).

Table 1. The demographic and economic profile of Guyana by Region.

Region	Population	Area (sq. miles)	Population density	Main economic activities
1	18,294	7,853	2,3	Fruit (avocado, citrus), agroprocessing (palmheart), biodiversity conservation, forestry*, roots and tubers*.
2	43,139	2,392	1,8	Rice, coconuts, fishing, fruits.
3	95,276	1,450	65,7	Rice, sugar, ground provision, fishing.
4	294,493	862	341,6	Rice, sugar, forestry, fishing, vegetables, livestock, forest products, processing, coconuts, craft.
5	51,274	1,610	31,8	Rice, sugar, logging, ground provision, vegetables, fruits, coconuts.
6	141,455	13,998	10,1	Rice, sugar, cattle, logging, vegetables, fruits, mining.
7	14,682	18,229	0,8	Mining (gold), small scale farming, balata, eco-tourism.
8	5,574	7,742	0,7	Mining (gold, diamonds), biodiversity conservation
9	14,947	22,313	0,7	Livestock, craft, peanuts, biodiversity conservation.
10	39,271	6,595	6,0	Mining, logging, farming, bauxite, livestock.

(Source: The Poverty Reduction Strategy Paper, Government of Guyana, 2005.)

*Note: These are additions to the original source.

Guyana's NDS is predicated on the basic principle that "*Guyana's development must not threaten the integrity of the environment*". In other words, the approach to development must be based on the "*prevention of environmental degradation, rather than on the application of remedial measures of doubtful efficacy, after the damage has already been done*" (see Box 3 below).

In another important State Paper, the Poverty Reduction Strategy Paper (PRSP) of the Government of Guyana (GoG) identifies reduction of poverty as an important pillar of national development. The PRSP reminds that despite abundant resources, Guyana is one of the poorest countries in the western hemisphere. Constraints to agricultural production and productivity have been identified as partly responsible for limited economic opportunities in Guyana. Low levels of manufacturing and value added, underdevelopment of eco-tourism, and inequities in the tax system were the other reasons of non-agricultural origin identified. At the macro-level, the Poverty Reduction Strategy (PRS) identified seven pillars, including broad-based, jobs-generating economic growth, and environmental protection as important to the reduction of poverty.

Box 3. The Four main objectives of the National Development Strategy.

- Rapid growth of incomes of the population in general.
- Poverty alleviation/reduction (rapid growth of the incomes of the poor).
- Satisfaction of basic social and economic needs.
- Sustainment of a democratic and fully participatory society.

Fundamental policy conditions for development in Guyana:

- Environmentally sustainable;
- Fiscally sustainable; and
- Institutionally sustainable.

(Source: National Development Strategy (2000). Government of Guyana.)

The PRS is consistent with the NDS and the UN Millennium Declaration in 2000 that committed countries – rich and poor – to *inter alia*, do all they can to eradicate poverty and achieve environmental sustainability, two of the Millennium Development Goals (MDG). Biotechnology offers an opportunity to strengthen links between growth and poverty reduction.

The importance of science and technology in national development is recognized. Lack of a reasonable level of science and technology capacity and opportunities have also been identified as critical to national development. Generally, the science and technology capacity of the nation, though experiencing a certain level of better recognition in the policy framework, needs serious attention and an immediate infusion of relevant and strategic resources. For a developing country, these are difficult decisions when faced with enormous basic socio-economic demands of the wider population amidst a serious effort by government to further reduce a poverty rate that is about one-third, through a well defined PRSP.

The draft national policy on science and technology is yet to be revised and finalized. The final document will reflect the need to leverage key and appropriate science and technology innovations for national development. The need for significant investments in the nation's science and technology infrastructure is well recognized. The need for an organizational structure to propel science, technology and innovation (STI) policy issues and actions through the reactivation of the National Science and Technology Council has been recognized. Although the Natural Resources and Environment Committee, a Sub-committee of the nation's Cabinet, has some oversight for science and technology issues in general, the well-considered view of the science and technology fraternity is the need for a dedicated national body to advance STI.

ICT4D Guyana National Strategy, a draft national strategy for leveraging information and communication technologies for development, was finalized in April 2006 after a very large gathering of participants in a national consultation. The ICT strategy identifies capacity building, the development of content and applications, improvement of infrastructure and connectivity, legislative and regulatory regime and the development of information technology enterprise as the major planks.

Box 4. Main Objectives of Guyana's ICT Strategy.

The overall objective of the Strategy is to accelerate economic growth and social development in Guyana. The specific objectives include:

- To promote the development of ICT services and businesses to increase job opportunities and generally to improve the economic and social well being of Guyanese.
- To improve the delivery at and access by all citizens to Government and other public services, including information on government activities and opportunities, public health, education and social development services.
- To improve the competitiveness of existing industries and to facilitate the sustainable development of new enterprises, thereby supporting economic diversification.
- To increase Guyana's international competitiveness in the delivery of goods and services to the global marketplace.
- To develop pertinent, strategic and focused network infrastructure to enable access to information and knowledge.
- To support national programmes and initiatives which foster social cohesion.
- To ensure access to reliable ICT at the lowest sustainable cost so that all Guyanese have the opportunity of participating in the information and knowledge society.
- To create a new generation of citizens that can use ICTs to leapfrog Guyana's development.
- To develop and implement the necessary policies, laws and regulations that support the sustainable development of the ICT sector.
- To modernize Guyana's Public Administration, Industry, Commerce and Communications sectors.
- To support initiatives to encourage innovation and creation in the ICT sector.

(Source: www.ict4d.gov.gy)

There are ongoing efforts to upgrade medical diagnostics within the healthcare sector in all administrative regions of Guyana. Additionally, at the time of updating this version of the draft NBF, the Ministry of Health unveiled a National Blood Safety Strategy in November 2006.

1.2.4 National relevance of the emerging global biotechnology and bioeconomy paradigm

Chapter 16 of Agenda 21 asserts that *biotechnology promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes*[2]. Three factors that would allow for wider participation of developing countries in scientific biotechnology are[3]:

- Growing recognition that current patterns of globalisation must be changed around to increasingly include developing country products;
- Many of the techniques used in biotechnology research are becoming readily available; and
- Much of the initial research and development expenditures have already been borne by the industrialised countries.

Biotechnology has become a cutting edge technology that is steadily increasing in its importance to economic development. This can readily be seen in the fields of food, agriculture and forestry, food processing, industry, health and the environment. Modern biotechnology enables scientists to increase the efficiency of breeding for some traditionally intractable agronomic problems such as drought resistance and improved root systems. Tissue culture has produced plants that are increasing crop yields by providing farmers with healthier planting material. Rice has been genetically engineered to contain pro-vitamin A (beta carotene) and iron, which could improve the health of many low-income communities.

In health, genetic engineering (GE) is helping to reduce the transmission of human and animal diseases through new vaccines. It makes possible the customisation of organisms or biological molecules for industrial or other practical purposes, such as the use of enzymes in washing powder. In industry, biotechnology is used in such varied contexts as producing drugs, bleaching paper pulp, extracting minerals, cleaning up oil spills and heavy metals in fragile ecosystems. Marker-assisted selection and DNA fingerprinting allow a faster and much more targeted development of improved genotypes for all living species. They also provide new diagnostic and research methods, which can assist in the conservation and genomic characterisation of biodiversity and related emerging infectious diseases, their vectors and causative pathogens.

1.3 NATIONAL INITIATIVES IN BIOTECHNOLOGY, BIOSAFETY AND BIOSECURITY

Plant tissue culture and natural products chemistry are the main forms of biotechnology practised in Guyana. Tissue culture is practised at the Biotechnology Unit of the National Agricultural Research

[2] The entire text of Agenda 21 is available at www.un.org/esa/sustdev/agenda21text.htm/.
[3] Juma and Konde (2002).

Institute (NARI)[4] and the latter at the University of Guyana (UG). The Unit at NARI provides micro-propagated plants of plantains (*Musa* spp.), pineapple (*Ananas comosus*), sweet potato (*Ipomoea batatas*), cassava (*Manihot esculenta*) and yam (*Dioscorea* spp.). The first four are included in the FAO biotechnology inventory as being in the commercial phase[5]. The Unit serves as the repository for the *in-vitro* storage of germplasm of these food plants. Research projects have included the development of laboratory protocols for *in-vitro* micropropagation and storage of cassava, pineapple, yam, sweet potato, plantains, tropical forest timber species and orchids; radiation treatment of *in-vitro* cultures of plantain to induce mutants with tolerance to Moko disease (*Pseudomonas solanacaerum*) and inducing salt tolerance in rice (*Oryza sativa*) lines.

NARI has a Virology Unit that utilizes a molecular (immunological) diagnostic procedure, ELISA (Enzyme-Linked Immunosorbent Assay), in the diagnosis of the Citrus Tristeza Virus. There is a Soil Microbiology Laboratory that has developed *Rhizobium* inoculant for use in legume biological nitrogen fixation (e.g. Octive *et al.*, 1993) and in the not too distant past, *Azolla* (10 strains) and blue green algae (nine strains) were maintained and characterised for nitrogen nutrition in rice.

Work has been done on bio-control in integrated pest management by NARI, Guyana Sugar Corporation (GuySuCo) and UG:

- In rice, control of stem borers *Diatraea* spp. and *Rupela albinella* Cramer, with the parasitoid *Allorhogas pyralophagus*;
- In sugarcane, control of giant moth borer, *Castnia licoides*, with the parasitic nematodes, *Beauveria* species, and *Metarhizium anisopliae*; control of the small moth borer *Diatraea centella* Moschler with parasitoids, e.g. *A. pyralophagus, Cotesia flavipes* and *Pediobus fervus;* control of the froghopper *Aeneolamis flavilatera* Urich with *M. anisopliae*; and, control of the grass species *Echinochloa pyramidalis*, using a fine grass. *Leersis hexandra* Swartz;
- In coconut, control of coconut caterpillar *Brassolis sophorae* using the entomopathogen *Beauveria* species.
- In various fruits and flowers, the control of the pink or hibiscus mealybug *Maconellicoccus hirsutus*, with the predator, the ladybird beetle, *Cryptolaemus montroazeiri* and the parasitic wasp *Anagyrus kamali* (Munroe. 1997); and
- In vegetables, aqueous extraction of neem (*Azadirachta indica*), mammey seed (*Mammea americana*) and jackbean (*Canavalia ensiformis*) for testing as anti-feedants.

Work has been done at the University of Guyana on biocontrol of mosquitoes using *Bacillus thuringiensis*. Additionally, some work has been done on a bioassay for determination of antibiotic concentrations in rabbit using the 4Q2 strain of *Bacillus thuringiensis*. Isolation of several fungal

[4] The work of this Unit is temporarily interrupted owing to the January 2005 floods. With the help of financial assistance from the Governments of the USA (through USAID) and Guyana, the Unit will be re-built as part of a project entitled ***"Management of plant genetic resources for food and agriculture"***.
[5] http://www.fao.org/biotech/inventory_admin/.

endophytes of notable timber species of Guyana have also been carried out[6]. The forte of the University has traditionally been bioassays for natural products derived from the rich local biodiversity.

Both UG and NARI have successfully cultivated edible mushrooms, *Pleurotus ostreatus*, *Lentinus* spp., *Ganoderma* spp., and *Auricularia* spp., under laboratory conditions on a range of locally produced substrates such as sawdust and coir or coconut fibre (NARI, 2000).

There is not currently or historically, direct use or application of biotechnology at the Guyana Forestry Commission (GFC) or by private forestry operators in Guyana, except phytohormone rooting experiments and agro-Rhizobia strain inoculation of wallaba (*Eperua grandiflora* ssp. *guyanensis*), and attempts at tissue culture of three forest species by the University of Guyana under the Tropenbos-Guyana forestry programme in the 1990s.

The only other project that may have some bearing or relation to biotechnology is the plantation project, which entails replanting of seeds and seedlings from trees that were logged or deforested. Biotechnology in the form of plant tissue culture would help to genetically alter the particular type of plant needed and the quantity as well. The GFC has interest in setting up a forest seed bank as well as storage and regeneration of forest plants using plant tissue culture techniques. FAO biotechnology inventory lists one entry, *Vouacapoua americana*, as being in the experimental phase[7].

1.3.1 Food processing biotechnologies

In the livestock industry, if a disease is detected, test samples are sent abroad for testing due to inadequate testing facilities in Guyana. At commercial poultry farms such as the Bounty Chicken Farm, HACCP (Hazard Analysis Critical Control Point) is in use and aids in securing good quality food products for consumers. Biosecurity is taken seriously especially at the hatchery. At the Guyana School of Agriculture Corporation (GSA), there is a well-established history of use of local herbs and spices in the preservation of meats, fruits and vegetables (e.g. David and Archibald, 1987).

Traditionally, the Amerindians and indeed other Guyanese, use casareep, an extract of bitter cassava, to preserve meats. Some work has been done at the University on the physico-chemical properties of this indigenous food additive and flavouring. Some preliminary work has also been attempted on the possible antimicrobial properties of casareep at the University.

[6] Cannon, P.F., and Simmons, C.M. (2002). Diversity and host preference of leaf endophytic fungi in the Iwokrama Forest Reserve, Guyana. *Mycologia. V*olume 94, pp 210 – 220.
[7] (www.fao.org/biotech/inventory.admin/).

1.3.2 Industrial biotechnologies

Biotechnology is used in the distillery and winery at Banks DIH and DDL. Alcohol is produced in two steps, fermentation and distillation. Fermentation relies on the use of yeast cells of *Saccharomyces cerevisiae* to ferment 80 ^{0}Brix sugarcane molasses. At DDL, biosafety is especially applicable to the juice plant (TOPCO) to aid in the prevention of contamination by native micro-organisms. While the company aims to introduce the HAACP system, a Cleaning in Place (CIP) system is in use and involves general sterilisation along with pasteurisation as a means of food safety. At the National Milling Company (NMC) and Guyana Stockfeeds Ltd., no modern biotechnology is applied. At the NMC, a bake test based on fermentation is used. GM wheat research is being monitored as a possible source of raw material for the flour industry.

Both UG and the Iwokrama International Centre for Rain Forest Conservation and Development have done some work done on natural products chemistry. At the UG Faculty of Natural Sciences, several M.Sc. theses were produced including titles such as “The manufacturing of paper from bagasse”, “The investigation of edible oils quality sold in a Georgetown Market”, and “Developing a protocol for increasing the shelf-life of coconut water”. It is not certain whether any of this research was converted to projects or enterprise for commercial gain, or otherwise used as the basis for further research.

1.3.3 Medical biotechnologies in the Health sector

Until recent times, no biotechnology was applied at the Ministry of Health or its departments FPD (Food Policy Division) or GA/FDD (Government Analyst/Food and Drugs Department). With the help of USAID and PAHO, the GA/FDD now has the molecular diagnostic capability to test for aflatoxin in peanuts and other crops and the diagnosis of organisms of microbiological important such as *Salmonella* species, *Escherichia coli*, *Enterococcus* species, *Pseudomonas* species, *Listeria monocytogenes, Vibrio* species, *Bacillus* species, yeasts and moulds. In addition, at the FPD, advice is given to personnel on safe disposal of waste products and to ensure product safety. At the GA/FDD, consumers are educated and provided information on foods produced by biotechnology or gene transfer. In nursing, there is no knowledge or technique of biotechnology currently in use.

1.3.4 Environmental biotechnologies

The Iwokrama Rainforest Centre has done work and offered training in bio-pharmaceuticals intellectual property rights (IPR), and access to genetic resources and benefit sharing (ABS). There is a draft policy document on IPR and ABS.

It is evident that lower-end biotechnology is applied in Guyana, but at present, with lesser intensity and extent given the cessation in operations of the plant biotechnology facility at NARI, the public institutional leader in biotechnology. There is definitely scope and numerous opportunities for

application of biotechnology to agriculture, health and the environment. Increased application of biotechnology would necessarily increase demand for biosafety and biosecurity. The suspected illegal introduction of GM tomato and corn to Guyana presents direct and indirect threats, the risks of which are yet to be assessed.

The University of Guyana's Biology Department has carried out a series of experiments evaluating the phytoremediation potential of a number of local plants including *Senna alata*. This institution is the hub of all the local phytoremediation studies so far.

1.4 NATIONAL CAPACITY BUILDING IN BIOTECHNOLOGY, BIOSAFETY AND BIOSECURITY PHYSICAL, AND INSTITUTIONAL INFRASTRUCTURE

This Framework (NBF) Project, in the words of the Honourable Prime Minister of Guyana, Mr. Samuel Hinds, is believed to "*take Guyana from a zero stage where national biosafety and biotechnology policies, biosafety laws and regulatory regimes are non-existent, to a stage where a draft national biosafety framework document with related draft biosafety legislation would have been prepared*"[8]. The GoG/UNDP Project on Capacity Building for the Management of Natural Resources and the Environment is currently implementing the outcomes of focus group discussions on pollution prevention and sustainable use of biodiversity. The Iwokrama International Centre has capacity in intellectual property rights, access to genetic resources and benefit-sharing; these are important challenges in biotechnology.

Recent surveys indicate the University of Guyana is the lead institution with the critical mass of expertise spanning a range of biotechnology disciplines despite NARI being the lead biotechnology institution. The University's cadre of persons with biotechnology training includes one who recently returned from a six-month sabbatical attachment to Kew Gardens learning molecular techniques. There are two with fungal biotechnology expertise, one with microbial recombinant DNA expertise, four with natural products chemistry expertise, one with forest biotechnology, phytoremediation and bioassay expertise, among others.

Annually, at least 21 final-year B.Sc. Biology students take a one-semester course in molecular biology and biotechnology. However, the laboratory resources are less than adequate for the acquisition of effective practical experience. An EU-funded project, jointly executed by the University with Iwokrama, Kew Gardens and the University of the West Indies, significantly enhanced the physical equipment capacity for natural products extraction and isolation of fungal endophytes[9]. However, a lot more capacity building is required.

[8] Feature address by the Honourable Prime Minister, Mr. Samuel Hinds, during the formal launching of the NBF, Georgetown. July 28, 2004.

[9] Cannon, P.F., and Simmons, C.M. (2002). Diversity and host preference of leaf endophytic fungi in the Iwokrama Forest Reserve, Guyana. *Mycologia, V*olume 94, pp 210 – 220.

At NARI, the approved USAID PL 480 project "Plant Genetic Resources for Food and Agriculture" will build capacity in scientists and technicians in molecular biotechnology, a follow-up to a national course on DNA techniques held during 2-4 May, 2001, at NARI.

The Animal and Plant Health Units of the Ministry of Fisheries, Crops and Livestock (MFCL) operate border and coastal surveillance programmes for pests and diseases of agricultural animals and crops essential to its statutory agricultural biosecurity function. There is no post-entry quarantine facility and the veterinary diagnostic facilities are not presently in use. The GA/FDD has recently acquired the equipment and training for laboratory technicians in testing for aflatoxins and other mycotoxins in peanuts and other foods.

1.5 NATIONAL RESEARCH PROGRAMMES IN BIOTECHNOLOGY, BIOSAFETY AND BIOSECURITY

Currently, in biotechnology, research on commercial trait selection in sweet potato germplasm using conventional on-farm methods is on-going at Kuru Kururu by NARI scientists. Also, on-going at NARI are bio-control activities for control of Acoushi (*Atta* spp.) ants on cropland in the excessively drained white sand ecosystem at Mainstay in Region 2 and thrips of boulanger (*Solanum melongena*) using plant extracts in bait preparation. At GuySuCo, routine bio-control of froghoppers and sugarcane stem borers is ongoing as part of integrated crop management.

The University of Guyana continues to engage in active research in natural products and related bioassays as well as phytoremediation and fungal (mushroom) technologies.

The Food and Drugs Department recently acquired equipment to screen for mycotoxins, predominantly aflatoxins.

The need for additional resources underlines the success of all these initiatives.

2. INTRODUCTION TO BIOTECHNOLOGY, BIOSAFETY, BIOSECURITY AND THE NBF

2.1 BASIC DEFINITION OF TERMS – BIOTECHNOLOGY, BIOSAFETY AND BIOSECURITY

In the Convention on Biological Diversity (CBD), **biotechnology** is defined as: *"any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".* This definition does not distinguish between traditional biotechnology and modern biotechnology. On January 29, 2000, the Conference of Parties to the CBD adopted a supplementary agreement, known as the Cartagena Protocol on Biosafety and commonly referred to as the Biosafety Protocol. Three years later, on the September 11, 2003, the Cartagena Protocol entered into force.

The Biosafety Protocol is more concerned with modern biotechnology and defines it as *"the application of in vitro (in a test tube or other laboratory environment) nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family that overcome natural, physiological, reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection"*. It is this latter definition that this Guyana's NBF adopts in its broadest sense for international harmonization.

Biosafety or biological safety is the term used to describe efforts to reduce and eliminate the potential risk resulting from biotechnology and its products[10]. The Biosafety Protocol embraces the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage. The precautionary approach is reflected in many of the provisions of the Protocol and has as its focus the protection of the environment: *"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental damage"*. Public concerns about the potential risks from the use of modern biotechnology have led to the formulation of biosafety policy guidelines.

Biosecurity or biological security is the exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health[11]. It covers all activities aimed at managing the introduction of new species and managing their impacts once introduced. Indeed, given the extant and emerging global threats, the definition of biosecurity has been expanded to include a more strategic and integrated approach that encompasses the policy and regulatory frameworks

[10] CBD website at http://www.biodiv.org/biosafety/faqs.asp.
[11] Tiakina Aotearoa – Protect New Zealand – The biosecurity strategy for New Zealand. 2003. 67p.

(including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and plant life, and health, including associated environmental risks.

Box 5. Biosafety and Biosecurity.

FAO, 2003, articulation of the biosecurity concept: Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. Biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes.

Barletta, Sands, Tucker, 2002, biosecurity treaty rationale: ... an international biosecurity convention, which would be distinct from the bioweapons treaty but would complement it by primarily addressing the threat of bioterrorism. In addition, the biosecurity convention should build on the on-going implementation of the 1992 Biological Diversity Convention and its 2000 Cartagena Protocol on Biosafety, which includes provisions for the safe handling, transfer, and use of genetically modified organisms.

Cartagena Biosafety Protocol, 2000, objective: In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

World Conservation Union (IUCN), 1999, definition of "biosecurity threats": means those matters or activities which, individually or collectively, may constitute a biological risk to the ecological welfare, or to the well-being of humans, animals or plants, of a country.

_____

(Source: Biosafety, Biosecurity, and Bioweapons: Three Agreements on Biotechnology, Health, and the Environment, and Their Potential Contribution to Biological Weapons Control - The Sunshine Project - Background Paper #11, October 2003. http://www.sunshine-project.org/publications/bk/bk11.html.)

Biosecurity covers the introduction (intentional and unintentional) of plant pests, animal pests and diseases, zoonoses, the introduction and release of Genetically Modified Organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes, as well as biological weapons and other agents used in biocrimes within the scope of agricultural bio-warfare and bioterrorism in general. In this context, human diseases and the entire spectrum of bioterrorism, related bio-arsenal and global pandemics are included within the scope of the NBF.

2.2 NATIONAL POLICY AND THE NATIONAL BIOSAFETY FRAMEWORK

The prevailing fundamental national environmental ethos which precedes the emergence of GMO's and related biosafety issues is enshrined in the nation's supreme law, *The Constitution of Guyana 1980*. Guyana's environmental ethos is articulated in Chapters 2:25 and 2:36 and Article 149J of the Constitution which state *inter alia*:

> ***"Every citizen has a duty to participate in activities to improve the environment and protect the health of the nation"*** [Chapter 2:25]
>
> ***"In the interest of the present and future generations, the state will protect and make rational use of its fauna and flora, and will take appropriate measures to conserve and improve the environment"*** [Chapter 2:36]
>
> ***"(1) Everyone has the right to an environment that is not harmful to his or her health or well-being (2) The State shall protect the environment for the benefit of present and future generations, through reasonable legislative measures deigned to (a) prevent pollution and ecological degradation; (b) promote conservation; and secure sustainable development and use of natural resources while promoting economic and social development."*** [Article 149J]

Emerging from these constitutional principles, the evolution of institutional and governance structures for the environment have led to the enactment of an *Environmental Protection Act 1996* [establishment of the EPA]; and the formulation of the *National Strategy for the Conservation and Sustainable Use of Guyana's Biodiversity 1997* [the first policy document to specifically mention GMO's, the transfer of biotechnology and encouragement of local initiatives without mentioning biosafety]; and the *National Biodiversity Action Plan, 1999.*

The National Biodiversity Action Plan (NBAP) was the first policy document to explicitly address the issue of biosafety and to propose the establishment of a molecular genetics laboratory at the University of Guyana as part of national capacity building initiative. The *National Development Strategy 2000,* though it identified a set of environmental philosophies and advocates a strong nexus between environment and development, does not specifically address biotechnology and related issues except in general terms of using technology for national advancement and development within the agricultural and manufacturing sectors.

A variety of broad statements relating to government policy on biotechnology and biosafety have been articulated in several speeches by key policy makers over the years. Some of these are captured in the GY-NBF consultancy report No.9 (Annex 8). Prior to the draft National Biotechnology, Biosafety and Biosecurity Policy, the most significant policy statements of the government have been those articulated by the second highest ranking policy-maker, the Prime Minister of the Republic, during the launching of this project in July, 2004 (Annex 9).

Essentially, Guyana articulates a policy for strategic biotechnology research, innovation, development and the leveraging of requisite technologies for the safe and sustainable use of its enormous per capita biodiversity wealth. The ultimate aim is for socio-economic enhancement and poverty alleviation without jeopardizing the health and welfare of the nations' environment and citizens as enshrined in the Constitution.

2.3 THE NATIONAL BIOTECHNOLOGY, BIOSAFETY AND BIOSECURITY POLICY

2.3.1 Basic principles of the Biotechnology, Biosafety and Biosecurity Policy

The ethos of national policy on biotechnology, biosafety and biosecurity is buttressed by the following seven principles:

1. Guyana has sovereign rights over natural or native (including genetic) resources in its area of jurisdiction, and authority to control activities which exploit or may have negative impacts on such resources.

2. Guyana shall endeavour to strike appropriate balance between biotechnology promotion and regulation in sustainable development pathway vis-à-vis organic agriculture and conservation of biodiversity.

3. Use, output, export, sale or transit of biotechnology applications, practices, and products must conform fully to all existing or anticipated national legislation.

4. Formal regulation of biotechnology shall be by a competent authority advised by a technical body independent of both government and industry whose decision-making process is transparent, takes full account of environment, public health, socio-economic, and socio-cultural concerns based on locally applicable scientific data, and applies the precautionary approach.

5. Biotechnology applications based on or inspired by the knowledge, innovations or practices of communities or individuals of Guyana shall be subject to national legislation(s) related to community or individual intellectual property rights and shall incorporate contractual agreements to share financial or other benefits arising from such applications with these communities or individuals. The state shall facilitate community access to appropriate advice for the purposes of negotiating and concluding such contractual agreements.

6. Guyana shall endeavour to cooperate with other states particularly its neighbours, to ensure the safe use of biotechnology within its borders and protection from illegal trans-boundary movements.

7. Guyana shall not permit the importation and use of biotechnology products and procedures which do not meet minimum safety standards identified by the competent authority as stated in this policy document.

2.3.2 Description of the National Biotechnology, Biosafety and Biosecurity Policy

Guyana's policy on biotechnology, biosafety and biosecurity aims to strengthen Guyana's capability to take advantage of the opportunities offered by biotechnology, for the benefit of the individual, industry and the environment. The biotechnology policy aims to promote the accumulation and use of knowledge in the sector, to facilitate the conversion of the results of research projects to practical applications, under ethically acceptable conditions, with the risks overcome and protection of the traditional sectors from the negative effects of some aspects of biotechnology. The policy encourages public-private sector partnerships and foreign direct investment. Guyana is an attractive country to do business in because of its rich biodiversity and indigenous resources.

The **objectives** of the proposed policy are two-fold:

1. Guide the judicious use of modern biotechnology in Guyana for sustainable development in ways, which do not jeopardise human or environmental health including Guyana's biodiversity and genetic resources.

2. Ensure effective control of trans-boundary movement of GMOs or products thereby resulting from modern biotechnology through exchange of information and a scientifically based, transparent system of advance informed agreement.

The **scope** of this policy covers all GMOs and their products, all LMOs and all elements of genetic materials used in genetic manipulation of any kind. This national policy covers in detail: laboratory and field applications of biotechnology within Guyana, the fields of agriculture, environmental management, food/beverage processing, health and industry, the regulatory processes, the biotechnology research and development process, occupational safety at work places where biotechnology procedures are used or products handled, labelling of GMOs in feedstuffs and feeds sold in or imported to or through Guyana and any other measures to ensure public safety or health or environmental safety with respect to the use of biotechnology in Guyana or its neighbouring territory or waters.

The four main policy issues for Guyana are how pervasive or strategic is biotechnology to the economy, dissemination of knowledge (public participation), human resources and social acceptance of the technology and/or its products. In the Guyanese public interest, policies can be positive, neutral or negative. In the case of biotechnology, the general lack of knowledge, present limited application of the technology and a high degree of suspicion suggest that a precautionary policy might be preferred at

this stage[12]. Adopting this approach means that the anticipated economic effects will be modest; but with application, effects on environment and quality of life can be much larger. Later, a promotional or permissive policy can be considered. The EP Act advocates the precautionary approach.

In a limited survey, respondents were adamantly cautious and rejected outright, some types of biotransformation. Zoning of a country for crops on the basis of genetic modification allows positioning to take advantage of both GM and non-GM markets. Such a policy will produce results only if there is low cost, and quick and reliable testing of the presence of GM germplasm at every point of the crop production chain. A certification programme[13] may offer an interim solution to safeguard the nation's organic agriculture market.

The wisdom adumbrated by OAS and the Millennium Development Taskforce on Science, Technology and Innovation enjoining countries of the Americas to increase their commitment to R&D in science and technology, establish collaborative effort at the hemispheric level (OAS), develop human resources and infrastructure, establish a legal framework within which biotechnology development may occur in order to achieve proficiency in biotechnology, is heeded.

The present Guyana policy identifies opportunities for wealth creation and national well being in the sectors of agriculture, food processing industry, health and the environment. The policy encompasses five pillars, which underline the direction and measures towards developing biotechnology and protecting the nation from the effects of GMOs and GE. The five pillars are:

I. Create and sustain public awareness of biotechnology, biosafety and biosecurity and increase the nation's human capital in biotechnology through education and training. There is no doubt biotechnology is built from the power of research and human intellect.

II. Establish biotechnology centres of excellence in selected parts of the country, where multi-disciplinary research teams work in coordinated initiatives, leading to the transformation of the productive sectors and commercialisation of the rich biodiversity.

III. Apply incentives to encourage committed participation from academia and the private sector.

IV. Review the legal and regulatory sectoral framework to protect traditional sectors.

V. Establish a dedicated and professional agency to spearhead the development of Guyana's biotechnology sector. The key aspect here is to employ an approach that moves away from an infrastructure focus to one that builds on the capabilities of existing institutions.

[12] Countries such as Kenya, Brazil and India have highly precautionary biosafety policy.
[13] The certification programme of the type developed by Iowa State University "Uniform Certification Procedure" is considered adequate in the present circumstances.

Emerging from the strategic pillars of the policy, the following may be surmised for the effective development and deployment of biotechnology, biosafety and biosecurity for the nation's bioeconomy thrust, namely:

i. Public awareness, education, access to information and training.
ii. Biotechnology centres of excellence.
iii. Incentives for bio-entrepreneurship.
iv. Legal and regulatory framework.
v. Institutional infrastructure and capacity development for leveraging biotechnologies.
vi. Indicators for monitoring biotechnology, biosafety and biosecurity development and capacity.
vii. Indicators for development and monitoring of biotrade and related regional and global competitiveness.

Additionally, the strategic use of the triad concept of biotechnology, biosafety and biosecurity in agricultural diversification, food security, environmental security, ecosystem health, improved health care, economic security and regional and global trade is fully recognized. Although the specific role of biotechnology in national development was not explicitly amplified in the recent *National Competitiveness Strategy 2006*, the incorporation of strategic biotechnology, biosafety and biosecurity initiatives would be imperative.

2.3.3 Strategic opportunities for leveraging safe biotechnology for development

The commercialisation of biotechnology in Guyana should seek to follow the model of other developing countries such as India, Cuba and Brazil, which provide good examples of leadership on technology matters, domestic funding for research activities, creation of appropriate research institutions and international alliances for product commercialisation. Some important commercial starting points include the production of enzymes (world market value of US$1.6B), amino acids and vitamins (world market value of US$3B), digestive enhancers (world market value of US$1.3B) and disease preventing agents (world market value of US$480M) (Juma and Konde, 2002). It is predicted that the market for probiotics, amino acids and digestive enhancers will grow.

Accordingly, potential market gains can be had from[14]:

- Bio-fertilisers – an affordable industry, cheap to manufacture and suitable for small-scale farmers if produced locally (eliminates distribution costs) and investment in technology is far lower than that of inorganic fertilisers;

- Body and health-care products (nutraceuticals) – demand is likely to increase. It presents a market for Guyana with its endowment of rich biodiversity;

[14] Juma and Konde (2002).

- Bio-preservatives – The food industry has failed to expand due to the continued use of chemical preservatives which many international markets are unwilling to accept. Use of natural products to inhibit bacteria and fungal growth will improve acceptability of products such as fruits and vegetables, fish and meat products. Most of the enzymes involved are easy to prepare in-house and can be obtained on the international market at a fair price; and

- Mining – could increase share of earnings if appropriate technology is developed. Use of bio-leaching technology can improve the quality of final products and reduce waste associated with mechanical cracking. Biotechnology solutions to mercury and cyanide use will increase value and earnings and reduce environmental degradation.

Consistent with Guyana's national policy statements would be approaches that add value to raw materials and present a means of indirectly marketing products that are currently difficult to sell.

Examples are:

- Conversion of cassava into export-products such as plastics, sweeteners, and fibres. Fibres or polymers can be used to make bags, plates and other utensils; and

- Conversion of wastes into useful products. Food wastes can be broken down into amino acids, fuels and fertilisers that will benefit rural and urban poor. The use of microbes and enzymes is key to this.

There are a number of current biotechnology products that are more expensive than traditional equivalents and care should be exercised in exploring them for commercial development[15]:

- Bio-pesticides – are still largely behind chemical pesticides due to target specificity (bad for business, good for the environment), instability and batch (potency) variation. Bio-pesticides are worth US$380M (or US$74M without Bt) out of an estimated US$8B pesticide market; and

- Bio-plastics and bio-fuels – are more expensive than traditional plastics and petroleum-derived equivalents in developed countries.

The provision of an enabling environment is key to allowing Guyana to participate effectively in the new biotechnology economy. The key determinants include market access, international biotechnology alliances, intellectual property protection, and regulation and risk management. Given the richness of Guyana's biodiversity, there ought to be a concerted effort to pursue activities that link biodiversity conservation and biotechnology such as: support for an open dialogue and consultation between stakeholder groups at the early planning stages of any activity involving transgenic organisms

[15] Juma and Konde (2002).

to identify potential environmental issues; build the capacity of in-country institutions to undertake regulatory research and environmental monitoring of biotechnology; and promote research to identify potential risks of biotechnology on specific aspects of natural biodiversity.

In addition, it is important for the public sector to retain enough capacity, resources and freedom of action to provide the services on which the national private sectors can build. They will also need to build their policy and regulatory capacities with regard to transgenic crops that originate elsewhere[16]. This framework cautiously posits the view that adequate research capacity is key to the appropriate development of biotechnology, including GM crops. Early evidence on farm-level impacts confirms that biotechnology applications may help poor farmers increase their productivity when, research is focused on smallholder problems, undertaken together with research to improve agronomic practices, and focuses on improved access to markets.

A recent report by the World Health Organisation entitled, "*Modern Food Biotechnology, Human Health and Development"*, notes that "pre-market assessments done so far have not found any negative health effects from consuming GM foods". However, the need for broader and continuing evaluation is emphasised as was illustrated in 2002 when several southern Africa countries facing food shortages did not permit GM food aid, citing socio-economic, ownership and ethical concerns rather than health or environmental ones[17].

2.4 THE NATIONAL BIOSAFETY POLICY FOR GUYANA

The biosafety policy covers all GMOs and their products, all LMOs and all elements of genetic materials used in genetic manipulation. This national policy covers in detail the following:

1. Laboratory and field applications of biotechnology within Guyana whether currently known to science or those developed in future.

2. The fields of agriculture, environmental management (including bioremediation of mining, industry and domestic wastes), food/beverage processing, health (including human and veterinary medicine) and industry, and other fields of current or future applications.

3. The regulatory processes, including notification, information transfer and review, risk assessment including socio-economic impact, ethical considerations, monitoring and enforcement measures pertaining to import or export of the products of biotechnology or laboratory or field use of biotechnology in Guyana including handling, disposal, containment, control, monitoring and release.

[16] In this area, the International Plant Protection Convention (IPPC) is establishing practical cooperation with the Convention on Biological Diversity and its Biosafety Protocol. It is also developing a detailed standard specification for an International Standard for Phytosanitary Measures that identifies the plant pest risks associated with Living Modified Organisms, and ways of assessing these risks.
[17] http:www.SciDev.Net 24 June 2005.

4. The biotechnology research and development process, including academic, agriculture, health, industrial and other research.

5. Occupational safety at work places where biotechnology procedures are used or products handled.

6. Labelling of GMOs in feedstuffs and feeds sold in or imported to or through Guyana.

7. Any other measures to ensure public safety or health or environmental safety with respect to the use of biotechnology in Guyana or its neighbouring territory or waters.

2.4.1 Thematic Areas of biosafety regulation policy emphasis

The areas of biosafety regulation emphasis will be the following:

- Agricultural biotechnology;
- Environmental biotechnology;
- Food (processing) biotechnology;
- Health biotechnology; and
- Industrial biotechnology.

2.5 THE NATIONAL BIOSECURITY POLICY FOR GUYANA

2.5.1 Biosecurity policy

Biosecurity is considered one of the most critical issues in the shaping of Guyana's future well-being. The need for public support cannot be underestimated. The carambola fruit fly detected in 1993 at Orealla was eradicated in 1998 with the combined use of IPM, quarantine restrictions and public awareness campaigns. The biosecurity focus ought to be on pre-border, border and post-border activities designed to keep out new pests, to maintain and monitor the framework for pest management agencies for industry and individuals to take collective action against pests as well as a framework for managing intentional introduction of new organisms including GMOs. Government should have overall responsibility for funding biosecurity, in particular, border management, surveillance and incursions.

The importance of biosecurity from the purview of international threats of bioterrorism is fully appreciated in the context of intended or unintended exposure. In securing the nation's stake in the Caribbean tourism economy, biosecurity in this context is considered of paramount import in securing the safety of all citizens and visitors. This aspect will require an enormous amount of resources and cooperation with other nations particularly in this hemisphere.

2.5.2 Goals of the biosecurity policy

1. Prevention and exclusion – preventing entry and establishment of pests and unwanted organisms capable of causing unacceptable harm to the economy, environment and people's health.

2. Surveillance and response – early detection, identification and assessment of pests and unwanted organisms capable of causing unacceptable harm and where appropriate, deployment of a rapid and effective incursion response that maximises likelihood of eradication.

3. Pest management – effective management (including eradication, containment and control) of established pests and unwanted organisms capable of causing harm to the economy, environment and people's health.

To achieve these goals, the biosecurity system needs to have these **elements**:

1. Strong global and regional relationships to identify and manage emerging risks.
2. Identify all risk pathways and high risk organisms and implementation of pre-border and border measures to prevent pests and diseases entering Guyana.
3. Comprehensive, competent surveillance programme and diagnostic services to detect and identify arrival and spread of pests and diseases.
4. Sufficient capability to conduct timely assessment of the threats for new or expanding species.
5. Rapid response capability to eradicate new pests and diseases before they establish and spread.
6. Seamless integration among the appropriate agencies of central, regional and local government, each with clear roles and accountabilities.
7. Effective strategies in place for eradicating, containing and controlling pests and diseases already established.
8. Effective eradication and awareness programme to encourage compliance with biosecurity rules and regulations.
9. Strong enforcement of our biosecurity laws.
10. Strong input of scientific advice at all levels of policy, planning and decision making.
11. A strong culture of continuous improvement.

The Biosecurity System is envisaged to cover the following pathways of pest transport and potential agro-terrorism and bioterrorism agents to Guyana:

- Imported goods;
- Ships and aircraft;
- Ship ballast water;
- Vessel hull fouling;
- Shipping containers;

- Used vehicles and machinery;
- Passenger's effects;
- Mail and courier packs;
- Smuggling; and
- Wind and ocean currents.

Under the Biosecurity system, pre-border and border activities are expected to be covered as follows:

1. Pre-border activities:
   Honour all international commitments under multi-lateral environmental agreements such as the CBD, the UN Convention on the Law of the Sea, and the Convention on Persistent Organic Pollutants (POPs). Pre-border activities shall include:
   - Testing;
   - Inspection; and
   - Treatment or quarantine.

2. Border (marine and terrestrial) and post-border activities:
   The objective of regulatory control is to prevent entry and establishment of new pests in a country or area and to destroy or prevent further spread of those already present. Plant/animal quarantine is concerned with preventing the spread of pests from country to country. It is the first line of defence against pest introduction and establishment. Such a system is based upon a combination of some or all of the following measures:
   - Prohibition or complete embargo;
   - Restriction or partial embargo;
   - Inspection and treatment at point of origin;
   - Inspection and certification at point of origin;
   - Inspection at point of entry; and
   - Utilisation of post-entry quarantine facilities especially for plant propagative or animal reproductive materials, which are the greatest risks from a plant/animal quarantine point of view.

In order to achieve the aforementioned, a Biosecurity Scientific Advisory Sub-Committee of the NBA (National Biosafety Authority) shall be established. This Sub-Committee shall comprise a specially trained and equipped team from the Plant and Animal Protection Unit of the MFCL (Ministry of Fisheries, Crops and Livestock) and shall be made responsible for the agro-biosecurity system. This will require amendments to the Plant Protection Act and Animal Disease Act to address the risks associated with GMOs and biosecurity issues identified in this document. The Ministry of Health shall be made responsible for other aspects of biosecurity in relation to biowarfare and other forms of bioterrorism which directly impact human health of both locals and tourists.

2.6 BIOSAFETY REGULATORY REGIME

Guyana has no specific overarching legal regulatory regime for biotechnology and biosafety although the EP Act requires the execution of an EIA for projects dealing with GMOs. There are no specific details of guidelines or procedures to be followed nor have specific GMO risk assessment procedures been elaborated. Nonetheless, several of the laws and legal instruments of Guyana impinge directly or indirectly on biosafety-related issues. The details of these national legal instruments as well as relevant regional and international instruments to which Guyana is signatory have been provided in Table 2.

A set of national legal instruments which directly relate to biosafety and GMOs through possible harmonization are:

- Environmental Protection Act No. 11 of 1996;
- Biosafety Bill [to be drafted];
- Biotechnology Research, Innovation and Enterprise Development Bill [to be drafted];
- Food Act [in draft];
- Food and Drugs Act CAP 34:01 of 1971;
- Pesticides and Toxic Chemicals Control Act No. 13 of 2000;
- Customs Act CAP 82:01 of 1952 Amendment No. 1 of 2005;
- Seed Regulation Bill [in draft];
- Crops and Livestock Registration Act CAP 68:04 of 1917;
- Plant Protection Act CAP 68:03 of 1942;
- Fisheries Act No. 12 of 2002;
- Guyana National Bureau of Standards Act CAP 90:16 of 1984;
- Animal Movement and Diseases Act No.14 of 2003;
- Animals (Control of Experiments) Act CAP 71:03 of 1957;
- Occupational Health and Safety Act No. 32 of 1997;
- National Agricultural Research Institute Act CAP 68:02 of 1984;
- University of Guyana Ordinance of 1963; and
- Caribbean Agricultural Research and Development No. 6 of 1988.

2.6.1 Environmental Protection Act No.11 of 1996

a) Status: Enacted in 1996.

b) Scope of regulation:
Regulation, monitoring and enforcement of environmental standards and the safeguarding of national ecosystems, resources, human and environmental health.

c) Procedures and content:
Specifically requires EIA for projects involving GMOs.

Overall, the Act is to ensure the effective management of the environment to enable conservation, protection, and sustainable use of natural resources; **to promote the public participation in planning for sustainable development**; to co-ordinate the environmental management activities of all persons, organizations and agencies; to establish, monitor and enforce environmental regulations; to prevent or control environmental pollution; to co-ordinate an integrated coastal zone management programme; **to ensure that any activity which may have an adverse effect on the environment be assessed before commencement and that such adverse effect be a consideration when deciding whether or not such activity should be authorised**; **to ensure the conservation of bio-diversity and its sustainable use; to establish a national parks and protected area system and a wildlife protection management programme**; to promote an appreciation of the environment and its role in social and economic development; to establish institutional networks locally, nationally, regionally and internationally; to advise the Minister on the criteria and thresholds of activity for specifying what may amount to a significant effect on the environment; to advise the Minister on matters of general policy relating to the protection, conservation and care of the environment and the impact of development; to perform such other functions pertaining to the protection of the environment as may be assigned to it by the Minister by or under this Act or any other law.

Impact Assessments necessary for – Part IV – Sections 10 and 11.
Required for the construction of any hotel, guest house or inn exceeding ten rooms; installation for hydro-electric energy production; construction of roads, harbours and airfields; Installations designed to hold or store liquid on long-term basis; installation for the treatment of waste water, industrial or domestic waste; the importing of any waste matter whether hazardous or not; t**he release, use or keeping of any genetically modified organisms (Section 7 Fourth Schedule – definition of projects**); the harvesting and utilization of forest resources; the extraction and conversion of mineral resources. Contents of assessments – Section 11(5). Powers in relation to projects – Section 12, 13 and 14. Offences including damage to the environment – Section 39.

Annex 2 presents a schematic flowchart of EPA's present system for environmental permit applications.

d) Responsible Agent/institution:
   - Minister with responsibility for the environment – Sections 6, 7 and 8; Powers to make regulations – Section 68;
   - Environmental Protection Agency – Section 3; Responsible for all agencies with potential environmental implications - First Schedule;
   - Environmental Appeals Tribunal – Section 53;
   - Environmental Assessment Board – Third Schedule; and
   - Environmental Trust Fund – Section 58 Investigators.

2.6.2 Biosafety Bill

[Annex 5]

a) Status: As preliminary draft by NPC.

b) Scope of regulation:
The overall regulation of biosafety, monitoring and enforcement of biosafety standards, risk assessment of GMOs and related products when relevant; and the safeguarding of national ecosystems, resources, animal, plant, human, and environmental health and ensuring the safe use of biotechnology and related products.

c) Procedures and content:
See Annex 5.

d) Responsible Agent/institution:
- Tripartite – sector Minister – Office of the President - Environment (Lead), Agriculture and Health;
- Environmental Protection Agency (Lead NEA for Biosafety);
- National Biosafety Authority;
- National Science and Technology Research Council (research and bioethics);
- Guyana Biotechnology Corporation (Lead NEA for biotechnology development);
- Food and Drugs Department – Ministry of Health; and
- National Codex Alimentarius Commission.

2.6.2 Biotechnology Research, Innovation and Enterprise Development Bill

[to be drafted]

a) Status: In process of drafting.

b) Scope of regulation:
Regulation, monitoring and enforcement of biotechnology research, innovation and enterprise development standards, and the safeguarding of national ecosystems, resources, animal, plant, human, and environmental health. Ensure the sustainable use of the nation's biodiversity through innovative research and bioenterprise development of biotechnology and related products.

c) Procedures and content:
To be based on draft Bill.

d) Responsible Agent/institution:
- Minister with responsibility for Science, Technology and Innovation;
- Guyana Biotechnology Corporation; and

- NBA for Biosafety clearance issues.

2.6.3 Food Act

[in draft]

a) Status: In draft.

b) Scope of regulation:
Regulation, monitoring and enforcement of food safety standards.

c) Responsible Agent/institution:
- Minister with responsibility for food safety – Health; and
- Food and Drugs Department.

2.6.4 Food and Drugs Act CAP 34:01 of 1971

a) Status: Enacted 1971.

b) Scope of regulation:
Monitoring and enforcement of food and drug composition and safety.

c) Procedures and content:
Section 2 - Food – includes any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food or drink for any purpose whatsoever.
- Drugs defined.
- Label defined.
- Power to request **particulars regarding the composition of food** - Section 3.
- Labelling – Packaging Section 6.

Importation:
Maintenance of Food Standards – Section 7.

Presumptions – Section 31

Ministerial Orders – list certain types of drugs.

d) Responsible Agent/institution:
- Minister of Health – Section 3 orders the furnishing of particulars, Section 20 - Powers; Section 25 – regulations; Committees - Section 26;
- Inspectors – Powers – Sections 21, 22, 23 and 24;

- Government Analyst – Section 24; and
- Food Advisory Committee – Section 26.

2.6.5 Pesticides and Toxic Chemicals Control Act No. 13 of 2000

a) Status: Enacted 2000.

b) Scope of regulation:
Monitoring and enforcement of all maters relating to pesticides and toxic chemicals used in the production and storage of any produce be it agriculture, apiculture, aquaculture, forestry, horticulture, animal husbandry, product preservation and the like.

c) Procedures and content:
- Definitions
  - Agriculture – production and storage of any **produce** which is grown for consumption or any other purpose and includes use of land for grazing, forestry and woodland, fish culture, bee culture, market gardening, horticulture and nurseries and animal husbandry;
- Label;
- Pesticides as defined (z);
- Produce – any crop grown for consumption or other use and includes anything ordinarily used or which may be used in the composition of food for man of feed for domestic and farm animals;
- Representative membership of the Board – Section 4(2);
- Licences – granted by the Board – Section 7;
- Promote public awareness – Section 7;
- Importation
  Registration and licences – Part IV – Import – Section 12; Sale – Section 13; Application – Section 16; and
- Prohibited pesticides.

d) Responsible Agent/institution:
- Minister – Powers to order particulars – Sections 18, 19, Section 32 – Regulations; Minister responsible for Health – Section 44;
- Pesticides and Toxic Chemical Control Board – Establishment and functions - Section 4; Functions – Section 7;
- Medical Examiner – Sections 26 and 30;
- Registrar – Section 6; and
- Inspectors - Sections 26, 27, 28 and 29.

2.6.6 Customs Act CAP 82:01 of 1952; Amendment No. 1 of 2005

a) Status: Enacted 1952 – several Amendments – Amendment No.1 of 2005.

b) Scope of regulation:
Tariffs and trade in commodities. Overall monitoring and enforcement of customs regulations – import and export of goods including:
- Treatment of LMOs for rating and dutiable purposes. Import duties – listing and treatment in the various schedules and categories;
- Live animals and animal products – Meat and Edible Meat Offals; Fish; Crustaceans and Molluscs; Dairy produce;
- Vegetable products;
- Animal and Vegetable fats and oils;
- Products of the Chemical and Allied Industries;
- **Lists of Prohibited Restricted Exports – listing includes LMOs;** and
- List of Prohibited and Restricted Imports.

c) Procedures and content:
- Treatment of LMOs for rating and dutiable purposes. Import duties – listing and treatment in the various schedules and categories
- Categories include Section 1 – LIVE ANIMALS: Animal Products – Chapter 1; Meat and Edible Meat Offals – Chapter 2; Fish, crustaceans and molluscs – Chapter 3; Dairy produce – Chapter 4;
- Section II - Vegetable Products;
- Section III - Animal and Vegetable fat oils;
- Section VI – Products of the Chemical and Allied Industries;
- Lists of Prohibited Restricted Exports – Part II – listing includes LMOs (Needs harmonization with relevant biosafety bill); and
- List of Prohibited and Restricted Imports.

d) Responsible Agent/institution:
- Minister of Finance;
- Guyana Revenue Authority; and
- Officers.

2.6.7 Seed Regulation Bill

[in draft]

a) Status: In draft.

b) Responsible Agent/institution:
- Minister of Agriculture.

2.6.8 Crops and Livestock Registration Act CAP 68:04 of 1917

a) Status: Enacted 1917.

b) Scope of regulation:
Registration of crops and livestock with oversight lists per schedule.

c) Procedures and content:
- Crops to be identified – Schedule;
- Land defined – Section 2;
- Returns of Numbers of livestock and types of crops in prescribed forms - Section 3; and
- Acreage requirements.

d) Responsible Agent/institution:
- Minister - Section 3(5) and 3(6); and
- Chief Agriculture Officer – Section 3(1) and Section 4 (power of entry)[Present designation – Chief crops and Livestock Officer].

2.6.9 Plant Protection Act CAP 68:03 of 1942

a) Status: Enacted 1942.

b) Scope of regulation:
Plant health, plant quarantine and phytosanitary measures.

c) Procedures and content:
- Prevention, eradication and control of diseases affecting plants;
- Animal Organisms – Section 2: "means any animal organism in whatever stage of existence such animal organism may be";
- Plants – Includes any tree, shrub, herb or vegetable; any cutting, bulb, bud or graft; and fruit or any other part of any plant;
- Vegetable Organism – vegetable organism in whatever stage of existence such organism may be;
- Disease –defined in Section 2 and can be extended by Ministerial Order;
- Quarantine of Nurseries – Section 9;
- Import - **Prohibition of Importation Order** – Schedule of materials including (1) Citrus Material from the United States of America; (2) raw coffee; (3) Grapefruit from Trinidad and of all citrus fruits from the remainder of the Commonwealth West Indian Islands; Rice seed (padi) unless written authorisation obtained;
- Export – Plant Protection (conditions of exportation) order – Certificate of inspection is required – Phytosanitary Certificate;

- Importation of fruits and vegetables regulations;
- Fruit – does not include nuts, or dried canned, candied or other preserved fruits;
- Vegetable – does not include plantains, Irish Potatoes, canned or preserved vegetables, or onions;
- Section 4 – regulations not applicable to (a) any fruit or vegetable imported from the British Islands, the Republic of Ireland, Canada, the United States of America or the Commonwealth territories of the West Indies (not including Bermuda and the Bahamas);
- Pineapples, citrus fruits, yams, sweet potatoes, or tannias which are imported from Suriname;
- Conditions of Importation Regulations; and
- Particulars of Plants.

d) Responsible Agent/institution:
   - Minister – Sections 3, and 4, Section 16. Regulation including "for prohibiting, restricting the importation into Guyana of any plant, vegetable organism or package;
   - Plant Protection Officer - Sections 6 and 7;
   - Chief Agriculture Officer – Section 4 Prohibition of importation Order; and
   - Comptroller of Customs – certificate from Chief Agriculture Officer.

2.6.10 Fisheries Act No. 12 of 2002

a) Status: Enacted 2002.

b) Scope of regulation:
   Monitoring and enforcement of all ocean and inland fisheries regulations in Guyana.

c) Procedures and content:
   - Fish defined in Section 2 – any aquatic animal, whether piscine or not, and includes shellfish, turtle, mollusc, crustacean, coral, sponge, echinoderm, holothurian, its young and its eggs;
   - Fisheries plan defined in Section 2; Particulars of the Plan provided for in Section 5. Activities involving LMOs may fall within the particulars of these plans; and
   - Licensing requirements for vessels and activities.

d) Responsible Agent/institution:
   - Minister – Section 2 - to whom matters are assigned. Section 3 - powers to make regulations;
   - Chief Fisheries Officer – Section 4;
   - Fisheries Advisory Committee – Section 6; and
   - Fisheries Officer – Powers and Duties Section 40.

2.6.11 Guyana National Bureau of Standards Act CAP 90:16 of 1984

a) Status: Enacted 1984.

b) Scope of regulation:
Monitoring and enforcement of all regulations pertaining to standards – metrology, labelling, packaging, among others.

c) Procedures and content:
- Establishment of a Bureau – Section 3, with specific objectives - Section 4, including: To formulate the policy to achieve the objectives for which the Guyana National Bureau of Standards was established; To advise the Minister on any matter incidental to this Act; To establish laboratories and other facilities for carrying out the objectives of the Guyana National Bureau of Standards; To prepare standards, specifications and codes of practice; To provide facilities for the testing of all products and materials; To determine the composition of materials when such information cannot be obtained elsewhere; To establish and manage a national laboratory accreditation system; To make such arrangement for the training of its staff as is necessary for the execution of its duties, and To do all things incidental to the performance of its functions as stated by the Act;
- Functions and powers – Section 15 – standards, codes of practice, as well as Section 16 - obtain any patents, inventions, concessions or licenses and any instrument conferring the rights to use information, and to develop, use, exercise, assign, transfer, or otherwise exploit the property, rights and information so acquired;
- Importation permits, examination of imports, and registration of importers – Sections 23, 24 and 25;
- Analysis - Section 32; and
- Rights to discoveries, etc – Section 41.

d) Responsible Agent/institution:
- Minister – Section 48;
- Guyana National Bureau of Standards – Section 3;
- National Standards Council – Manages the Bureau, Section 5; Section 15 – Functions; and
- Inspectors – Section 27; Powers – Section 31.

2.6.12 Animal Movement and Disease Prevention Act No.14 of 2003

a) Status: Enacted 2003.

b) Scope of regulation:
Monitoring and enforcement of all regulations pertaining to the health and movement of animals including disease epidemics and quarantine procedures.

c) Procedures and content:
   - Animal defined - Section 2 “any non – human mammal, bird, fish, reptile, amphibian, crustacean or insect”;
   - Animal Product;
   - Animal Parts;
   - Free zone;
   - Restriction on Importation - Section 4;
   - Permit Necessary - Section 5;
   - Export of Animals – Section 7; and
   - Animal Quarantine – stations - Section 8, and quarantine of Animals - Section 9.

d) Responsible Agent/institution:
   - Minister – Minister responsible for Crops and Livestock. Declaration of Infected areas – Section 13 and free zones – Section 15, Section 16 – Emergency measures, and Section 24 - regulations.
   - Section 20 – Power of entry and search for inspector; and
   - Veterinary Authority – Section 3 (administration), Section 22 - Animal welfare.

2.6.13 Animals (Control of Experiments) Act CAP 71:03 of 1957

a) Status: Enacted 1957.

b) Procedures and content:
   - Defines “animal” as any living vertebrate animal. – Section 2;
   - Experiments relating to animals only performed by licensed persons and premises – Persons - Section 3;
   - Licenses;
   - Experiments by specific bodies.- Section 5;
   - Section 6 – Restrictions upon experiments;
   - Permits; and
   - Records of Experiments and returns – Section 11.

c) Responsible Agent/institution:
   - Minister – Section 7 – Grant of licence;
   - Chief Medical Officer – granting of permits – Sections 8 and 9; and
   - Inspectors – Section 12.

2.6.14 Occupational Health and Safety Act No. 32 of 1997

a) Status: Enacted 1997.

b) Scope of regulation:
Monitoring and enforcement of all regulations on occupational safety and health including work with biological agents which are defined as bacteria, viruses, fungi, rikettsiae, Chlamydia and parasites; critical substance - hazardous biological agent as well as hazardous chemical substances.

c) Procedures and content:
- Safety on premises relating to all industrial activities including agricultural undertakings;
- Provides relevant definitions – Section 2;
- Biological agent means bacteria, viruses, fungi, rikettsiae, Chlamydia and parasites; critical substance - hazardous biological agent – hazardous chemical substances;
- Applicable to industrial establishments;
- Register of industrial establishments – Sections 6 and 7;
- Use of hazardous chemicals, physical agents and biological agents – PART VI – Sections 59, 60 (new chemicals, etc.);
- Data and safety sheets – Section 63; and
- Assessment of hazardous chemicals – Section 64.

d) Responsible Agent/institution:
- Minister – Power to make regulations. – Section 75;
- National Advisory Council on Occupational Safety and Health – Section 10;
- Occupational Safety and Health Authority – Section 12; powers provided for in Section 13;
- Safety Advisory Board;
- Inspectors;
- Medical inspectors – Section 15; Section 16 – powers; and
- Occupational Safety and Health Commissioner – Section 21.

2.6.14 National Agricultural Research Institute Act CAP 68:02 of 1984

a) Status: Enacted 1984.

b) Procedures and content:
- Advice and development of agriculture towards achieving optimized production;
- Facilitate improved use of technology;
- Strengthen Exports of products; and
- Discoveries and inventions.

c) Responsible Agent/institution:
- Minister of Agriculture;
- Agriculture Research Committee; and

- National Agriculture Research Institute of Guyana – Section 12.

2.6.15 Caribbean Agricultural Research and Development No. 6 of 1988

a) Status: Enacted 1988.

b) Scope of regulation:
This Act operates within the scope of the regional Caribbean Community *Treaty of Chaguaramas*. Gives legal effect to the operations of CARDI in Guyana;

c) Procedures and content:
- Agreement for the Support for all agriculture research in the Caribbean Region. Schedule to the Act;
- Article 3 – Objectives of the Institute include: (a) to provide for the research and development needs of the agriculture of the **Region** as identified in national plans and policies; (b) to provide appropriate research and development service to the agriculture sector of Member States; (c) to provide and extend the application of **new technologies** in the production, processing, storage and distribution of agricultural products of Member States.
- ***Post facto* note:**
Lead agency for CARICOM's mandate on biotechnology and biosafety is CARDI, which chairs a Regional Biotechnology Working Group hosted by the Community's Secretariat. This Working Group reports to COTED. A regional approach to biotechnology and biosafety has been mooted within the context of the Caribbean Single Market and Economy (CSME) which is a regional legal instrument that was enacted in 2006.

d) Responsible Agent/institution:
- Minister with responsibility for Agriculture.

Table 2. The Laws of Guyana in relation to the requirements of the Cartagena Protocol on Biosafety.

Direct Biosafety-related laws of Guyana	**Relevant Cartagena Protocol Article(s)**	**Other relevant Regional and International Agreements, Conventions and Treaties**
	Article 11 "PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING **Article 15** - RISK ASSESSMENT **Article 18 -** HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION **Article 18(2)(a**) Each Party shall take measures to require that documentation accompanying: (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. **Article 19(1)** **COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS**	**Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. [The United Nations Framework Convention on Climate Change; The Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer.] **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region Cartagena.** **Article 5** - POLLUTION FROM SHIPS. **Article 6** - POLLUTION CAUSED BY DUMPING. **Article 7** - POLLUTION FROM LAND-BASED SOURCES. **Article 8** - POLLUTION FROM SEA-BED ACTIVITIES. **Article9** -AIRBORNE POLLUTION. **Article12** - ENVIRONMENTAL IMPACT ASSESSMENT (1). **Protocol Concerning Specially Protected Areas and Wildlife (SPAW)** ➢ **Article 13** ENVIRONMENTAL IMPACT ASSESSMENT. **WTO Agreement on Sanitary and Phytosanitary Measures**.

		Article 4 *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **The Convention to Combat Desertification**. **Article** 8 - Relationship with other Conventions. **Article 17** - Research and development. **Article 19** - Capacity building, education and public awareness. ANNEX III REGIONAL IMPLEMENTATION ANNEX FOR LATIN AMERICA AND THE CARIBBEAN. **Treaty for Amazonian Cooperation 1978.** ***Article VII*** - Taking into account the need for the exploitation of the flora and fauna of the Amazon region to be rationally planned so as to maintain the ecological balance within the region and preserve the species, the Contracting Parties decide to: Promote scientific research and exchange information and technical personnel among the competent agencies within the respective countries so as to increase their knowledge of the flora and fauna of their Amazon territories and prevent and control diseases in said territories. **Treaty of Chaguaramas.** **Caribbean Single Market and Economy.**
Biosafety Bill [drafted]	**All Articles of the Protocol**	**Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts.

		Codex Alimentarius. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region Cartagena.** **Article 5** - POLLUTION FROM SHIPS. **Article 6** - POLLUTION CAUSED BY DUMPING. **Article 7** - POLLUTION FROM LAND-BASED SOURCES. **Article 8** - POLLUTION FROM SEA-BED ACTIVITIES. **Article9** -AIRBORNE POLLUTION. **Article12** - ENVIRONMENTAL IMPACT ASSESSMENT. **Protocol Concerning Specially Protected Areas and Wildlife (SPAW).** **Article 13** - ENVIRONMENTAL IMPACT ASSESSMENT. **WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5****- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **The Convention to Combat Desertification**. ➢ **Article** 8 - Relationship with other Conventions. ➢ **Article 17** - Research and development, ➢ **Article 19** - Capacity building, education and public awareness. ANNEX III REGIONAL IMPLEMENTATION ANNEX FOR

		LATIN AMERICA AND THE CARIBBEAN. **Treaty for Amazonian Cooperation 1978.** ***Article VII.*** **Treaty of Chaguaramas.** **Caribbean Single Market and Economy.**
Biotechnology Research, Innovation and Enterprise Development Bill [to be drafted]	**All articles of the Protocol**	**Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Codex Alimentarius.** **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region Cartagena.** **Article 5** - POLLUTION FROM SHIPS. **Article 6** - POLLUTION CAUSED BY DUMPING. **Article 7** - POLLUTION FROM LAND-BASED SOURCES. **Article 8** - POLLUTION FROM SEA-BED ACTIVITIES. **Article9** -AIRBORNE POLLUTION. **Article12** - ENVIRONMENTAL IMPACT ASSESSMENT.

		Protocol Concerning Specially Protected Areas and Wildlife (SPAW). **Article 13** - ENVIRONMENTAL IMPACT ASSESSMENT. **The Convention to Combat Desertification**. **Article** 8 - Relationship with other Conventions. **Article 17** - Research and development. **Article 19** - Capacity building, education and public awareness. ANNEX III REGIONAL IMPLEMENTATION ANNEX FOR LATIN AMERICA AND THE CARIBBEAN. **Treaty for Amazonian Cooperation 1978.** ***Article VII.*** **Treaty of Chaguaramas.** **Caribbean Single Market and Economy.**
Food Act [in draft]	**Article 3 (g), (h), (i)** (g) "Living modified organism" definition. (h) "Living organism" definition. (i) "Modern biotechnology" definition. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 18** – Handling Transport, packaging and identification. **Article 23 -** Public awareness	**Codex Alimentarius.** **WHO Food and drug safety standards.** **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **The Basel Convention on the control of transboundary movements of hazardous wastes**

	and participation. **Article 25** - Illegal Transboundary Movements.	**and their disposal.** **Caribbean Single Market and Economy.**
Food and Drugs Act CAP 34:01 of 1971	**Article 18:** HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 23 -** Public awareness and participation. **Article 25 -** Illegal Transboundary Movements.	**Codex Alimentarius.** **WHO Food and drug safety standards.** **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection* ***Article 8*** *- Control, Inspection and Approval Procedures -* **The Basel Convention on the Control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Pesticides and Toxic Chemicals Control Act No. 13 of 2000	**Article 5** **PHARMACEUTICALS** "Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations."	**The United Nations Framework Convention on Climate Change.**. The Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer. The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal. **WTO Agreement on Sanitary and Phytosanitary Measures**. **The Convention to Combat Desertification.**

		Caribbean Single Market and Economy.
Customs Act CAP 82:01 of 1952 Amendment No. 1 of 2005	**Article 3 (g), (h), (i)** (g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; (h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids; (i) "Modern biotechnology" means the application of: (a) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 18** – Handling Transport, packaging and identification. **Article 25 -** Illegal Transboundary Movements.	**The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).** ***Article III*** **- Regulation of Trade in Specimens of Species Included in Appendix I.** ***Article IV*** **- Regulation of Trade in Specimens of Species Included in Appendix II.** **The United Nations Framework Convention on Climate Change.** **The Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer.** **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **WTO Agreement on Sanitary and Phytosanitary Measures**. **The Convention to Combat Desertification.**
Seed Regulation Bill [in draft]	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary*

	Article 13 – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 23** - Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	*Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Crops and Livestock Registration Act CAP 68:04 of 1917	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 23** - Public awareness and participation. **Article 25** Illegal Transboundary Movements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the* ***Appropriate Level of Sanitary or Phytosanitary Protection.*** ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Plant Protection Act CAP 68:03 of 1942	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.**

	Article 15 – Risk assessment. **Article 16** - Risk management. **Article 23 -** Public awareness and participation. **Article 25** Illegal Transboundary Movements.	**Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Fisheries Act No. 12 of 2002	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 23 -** Public awareness and participation. **Article 25** Illegal Transboundary Movements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Codex Alimentarius.** **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Guyana National Bureau of Standards Act CAP 90:16 of 1984	**Article 3 (g), (h), (i)** Definition of LMO. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 23 -** Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	**International Standards. Organization guidelines.** **WTO Agreement.** **Codex Alimentarius.**
Animal Movement and Diseases Act No.14 of 2003	**Article 3 (g), (h), (i)** Definition of LMO.	**WTO Agreement on Sanitary and Phytosanitary Measures**.

	Article 11 – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16 -** Risk management. **Article 23 -** Public awareness and participation. **Article 25 -** Illegal Transboundary Movements.	***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Animals (Control of Experiments) Act CAP 71:03 of 1957	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 19** – Information sharing and BCH. **Article 21** – Confidential information. **Article 22** – Capacity-building. **Article 23-** Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Occupational Health and Safety Act No. 32 of 1997	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary*

	Article 13 – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 19** – Information sharing and BCH. **Article 21** – Confidential information. **Article 22** – Capacity-building. **Article 23-** Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	*Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
National Agricultural Research Institute Act CAP 68:02 of 1984	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 19** – Information sharing and BCH. **Article 21** – Confidential information. **Article 22** – Capacity-building. **Article 23-** Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
University of Guyana (Amendment) Act 1995	**Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 15** – Risk assessment. **Article 22** – Capacity-building. **Article 23 -** Public awareness and participation.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection* ***Article 8*** *- Control, Inspection and*

		Approval Procedures. **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**
Caribbean Agricultural Research and Development No. 6 of 1988	**Article 3 (g), (h), (i)** Definition of LMO. **Article 11** – Procedure for use of LMO as food, feed or for processing. **Article 13** – Simplified Procedure. **Article 14** – Regional Agreements and Arrangements. **Article 15** – Risk assessment. **Article 16** - Risk management. **Article 19** – Information sharing and BCH. **Article 21** – Confidential information. **Article 22** – Capacity-building. **Article 23** - Public awareness and participation. **Article 25** - Illegal Transboundary Movements.	**WTO Agreement on Sanitary and Phytosanitary Measures**. ***Article 4*** *– Equivalence.* ***Article 5*** *- Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.* ***Article 8*** *- Control, Inspection and Approval Procedures.* **Convention on Biological Diversity.** **Article 10** - Sustainable Use of Components of Biological Diversity. **Article 14** - Impact Assessment and Minimizing Adverse Impacts. **The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal.** **Caribbean Single Market and Economy.**

2.7 CURRENT LEGISLATIVE SITUATION

Guyana has a plethora of laws and regulations but none presently fulfils the entire spectrum of requirements of the Cartagena Protocol on Biosafety. Though the EP Act of 1996 articulates an EIA requirement for GMO projects, the details for such a complex process have never been defined or tested. Contextually, the EP Act is premised on five principles of environmental management for the determination of environmental impact and risk, namely:

- The "Polluter pays" principle;
- The "Precautionary" principle;
- The "Strict liability" principle;
- The "Avoidance" principle; and
- The "State of technology" principle.

Within the above construct, the present system for environmental assessments as per EPA guidelines has a series of requirements (see Box 6 below). Also, a comparative analysis of existing EIA legislation in the Commonwealth Caribbean is presented in Table 3.

Box 6. The Environmental Assessment (EA) System of Guyana.

The Guyana EA System

The EA is categorised as a component of the EIA together with, environmental baseline study (EBS) and the environmental impact statement (EIS) and is defined as "basically the identification and assessment of impacts of the proposed project and of its alternatives" (EPA, 2000). In this regard, the EA encapsulates mitigation measures needed to offset any negative impacts as well as the assessment of the possible impacts of implementing mitigation measures on the environment. According to the generic EIA guidelines of the EPA, the EA should provide the following:

- Results of the regulatory and public participation programme;
- Identification, description and assessment of alternatives in relation to siting, processing, technology selection and reclamation;
- Detailed information regarding methods used to identify impacts (EIA methods) and the techniques used to estimate the magnitude of the impacts (prediction techniques);
- Identification, characterisation, description and determination of the magnitude and importance of the social distribution of the potential impacts in the short-, medium- and long-term;
- Analysis of the compatibility of the proposal with the existing environmental legislation that applies to the project itself or to its area of influence;
- Assessment of the physical effects for all phases including construction, operation and closure. This includes the estimation by type and quantity of expected contaminants, residues, and emissions (water, air and soil pollution, noise, radiation and heat) resulting

from the operation of the proposed project;

- Placement of special emphasis on indirect impacts which may arise from project implementation;
- Identification of how much of a particular resource is degraded or eliminated, and how quickly the natural system may deteriorate;
- Identification of how much a particular resource is degraded or eliminated, and how quickly the natural system may deteriorate;
- Assessment of the biological effects on the ecosystems of all project phases (construction, operation and closure);
- Assessment of the positive and negative impacts on land use, future development, cultural/historic resources (archaeology), indigenous peoples, demographics, infrastructure, employment, income, skills and education, and public health;
- A description of any hazards or dangers which may arise from the project and an assessment of the risk to the environment;
- Assessment of the project with a view to the need to protect and improve human health and living conditions and the need to preserve the stability of ecosystems as well as the diversity of species;
- Detailed information regarding measures which the proposed developer intends to use to mitigate any adverse effects and a statement of reasonable alternatives (if any), and reasons for their rejection;
- An assessment of worker health and safety; and
- Assessment of mitigation measures including cost/benefit analysis and implementation strategy.

(Source: www.unep.org/bpsp/EIA/Case Studies/Guyana (EIA).pdf)

The current legislative framework for natural resources management is presented graphically in Figure 2. It involves a variety of legal instruments, institutions and processes.

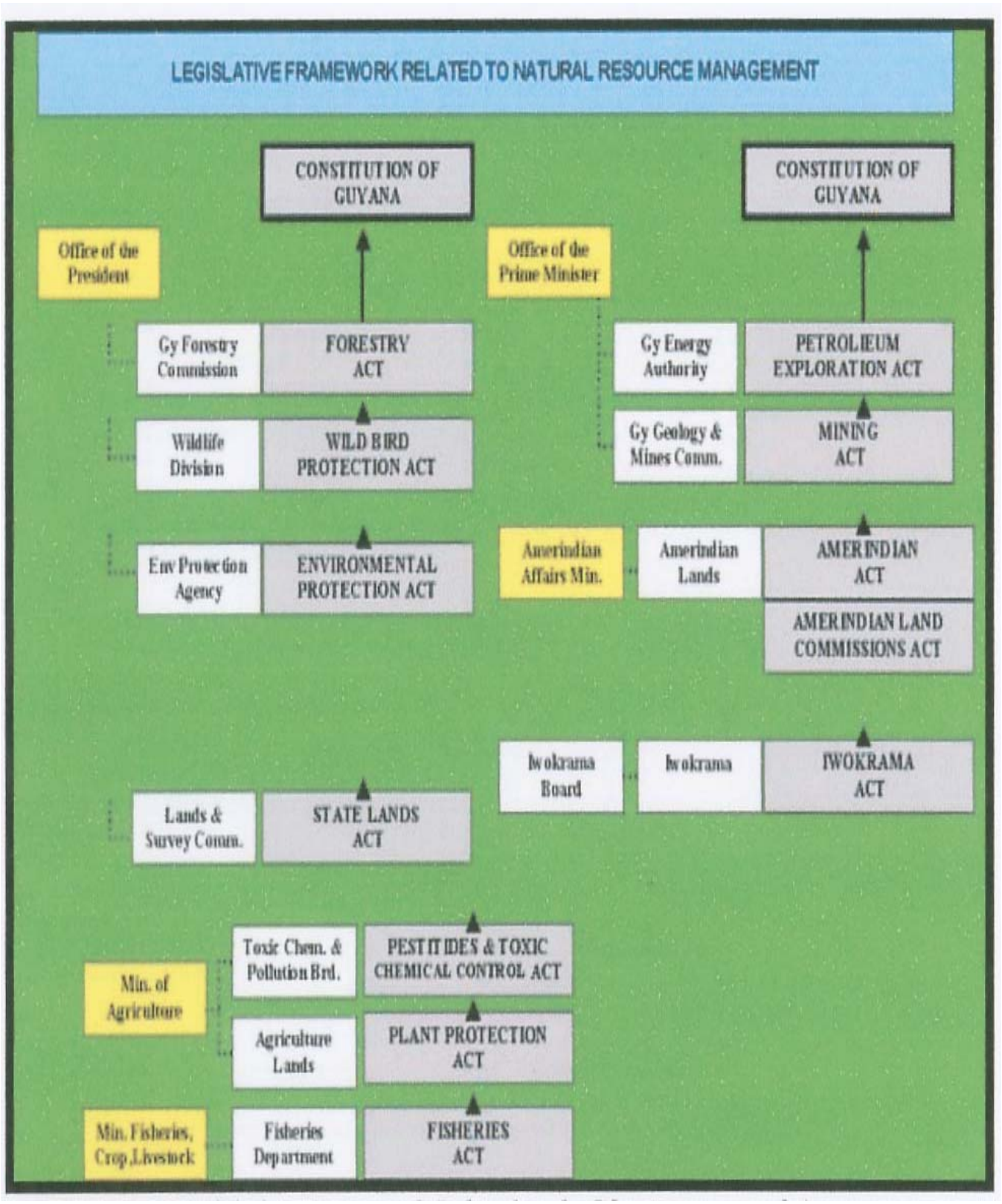

Figure 2. Current legislative framework for the management of natural resources in Guyana.

Emerging negotiations on the liability and redress aspects of the Protocol vis-à-vis the WTO agreement and its most recent ruling on GMOs, places an enormous legal burden on how best to implement the EP Act in its present form on biosafety regulation. The regulation of biotechnology cannot be achieved within the scope of the present EP Act and several other Acts with direct or indirect relatedness to biosafety or biotechnology. The need for a well defined specific regulatory framework for biosafety, biotechnology and biosecurity in harmony with the existing laws is recognized. Additionally, where existing laws need harmonization with the new Biosafety Bill as well as the Biotechnology Research, Innovation and Enterprise Development Bill, these must be done. A series of such harmonizable current laws have been identified as per Table 2. A comparative analysis of existing EIA legislation in the Commonwealth Caribbean is also presented in Table 3.

Table 3. Comparative Analysis of existing EIA legislation in the Commonwealth Caribbean.

Characteristic	Jamaica	Belize	Guyana	Trinidad & Tobago
Applicable law	Natural Resources Conservation Authority Act 1991.	Environmental Protection Act 1992 & Environmental Impact Assessment Regulations 1995.	Environmental Protection Act 1996.	Environmental Management Act 1995 (re-enacted 2000); Certificate of Environmental Clearance (Designated Activities) Order 2000 & Certificate of Environmental Clearance Rules 2000.
Agency responsible	Natural Resource Conservation Authority (NRCA).	Department of the Environment (DOE). Ministry of Tourism & the Environment.	Environmental Protection Agency (EPA).	Environmental Management Authority (EMA).
In which cases is EIA required?	Any existing or proposed enterprise, construction or development of a prescribed category in a prescribed area.	Mandatory list. Discretionary list. Exclusionary list.	Any project on a mandatory list and any other project which may significantly affect the environment.	Any listed activity designated as one for which a CEC is required.
Is there a formal screening process?	No provision.	Responsibility assigned to DOE, no procedure	Responsibility assigned to EPA, no procedure	Responsibility assigned to EMA, no

		specified.	specified but Minister may make Regulations establishing criteria and thresholds.	procedure specified.
How is the scope or TOR of the EIA determined?	NRCA to prescribe information required and applicant must comply.	Developer to prepare draft TOR for review by DOE and modify same if DOE requires. TOR agreed between developer and DOE to be approved by DOE.	EPA must publish decision that EIA is required; EPA sets TOR after consultation with EIA preparer, taking into account any written submission made by public.	EMA prepares draft TOR; Developer may submit written representations for modifications after consultation with relevant agencies, NGOs and members of the public; EMA issues final TOR.
Can a conceptual approval be obtained before EIA has been completed?	No planning permission or other approval may issue until NRCA has granted or given notice that it plans to grant a permit.	Developer shall not commence or proceed with the project until advised on DOE's decision.	No other agency may grant any development consent that entitles the developer to proceed unless environmental permit has been issued by EPA.	No other agency can grant any documentary authorization with respect to the activity until a CEC has been issued by the EMA.
Who does the EIA?	No provision.	Developer is responsible for EIA; EIA must be carried out by a "suitably qualified person".	EPA required to compile list of approved persons with assistance of internationally recognized NGOs, only approved persons may prepare EIAs.	EIA to be carried out by persons with expertise and experience in the specific area for which information is required.
Must the state provide information to the developer?	No provision.	Developer may obtain guidelines fro preparing EIA from DOE for a minimal fee.	EPA must carry out environmental studies to make information available to public upon payment of photocopying cost.	No provision.
What is the role of the public in the EIA process?	No provision.	Developer must hold public meetings during preparation of EIA; DOE may invite specific	Notice published before EIA begins; public may make written submissions re scope; during	Any application for which EMA requires an EIA must be submitted for comment before

		stakeholders to raise concerns; procedures to be decided by DOE; Developer to publish notice that EIA has been submitted. EIA report to be available for inspection during prescribed periods; DOE may direct developer to send copies to specific stakeholders; deadline for public comments; DOE may require a public hearing on advice of the NEA committee.	course of EIA preparer must consult with stakeholders and release information obtained at photocopying cost. Developer must publish notice when EIA submitted; public may submit comments; EA board may conduct public hearings on EIA; EIA deemed public document to be kept available by Developer and EPA for public scrutiny for duration of project plus five years; EPA to maintain public register of all EIAs.	a CEC is issued; not less that 30 days must be allowed for the submission of written comments; EMA may hold public hearing if there is sufficient public interest in the matter; the administrative record and copies of the final action must be kept available top the public for not less than 45 days after the decision is published.
How is the EIA evaluated?	No provision.	DOE examines EIA for compliance with TOR; NEA Committee reviews EIA and advises DOE on adequacy; may advise DOE to hold public hearings.	EPA responsible for evaluation; but must submit EIA to EA board for consideration; EA board conducts public hearings, if necessary, and makes recommendations to EPA.	No provision.
What is the outcome of the process?	Permit issued by NRCA.	"Decision" by DOE whether project may proceed.	Environmental Permit issued by EPA.	Certificate of Environmental Clearance (CEC) issued by EMA.
Is there and avenue for appeal?	Appeal to the Minister if permit refused or approved conditionally.	Developer may appeal DOE's decision to the minister; minister appoints tribunal to hear appeal; tribunal reports to Minister;	A person affected by a project exempted from EIA requirements may appeal to EA board; Developer may appeal against requirement for	Any participant may appeal about failure to comply public participation requirements; applicant may appeal final

		Minister's decision is final.	EIA or refusal to permit to EA tribunal (special court); and form there to Court of Appeal on point of law.	decision on CEC to environmental commission (special court); and from there to Court of appeal on point of law.
Who pays?	Minister may prescribe fees payable.	No provision.	All expenses of EIA process to be borne by the developer.	Minister may prescribe fees payable.
Is there a timeline for the process?	NRCA sets deadline for completion of EIA.	DOE has 30 days to decide if EIA required; Developer must submit EIA by prescribed date; public comment period to be prescribed in notice; DOE must advise Developer of decision within 60 days after EIA submitted; Developer must appeal within 30 days thereafter.	28 days allowed for public comments on scope of EIA; 60 days allowed for 3rd party appeals against EPA decision to exempt project from EIA. 60 days allowed submission of public comments on EIA & EIS.	EMA has 10 days to decide if EIA required & 21 days to prepare draft TOR; Developer has 28 days to request modifications; EMA has 10 days to finalise TOR; minimum of 30 days must be allowed for public comment; EMA must give decision on CEC within 30 days after EIA submitted.

2.8 NEW BIOSAFETY REGULATORY REGIME AND NEEDS

2.8.1 Institutional framework

The institutional framework for the administration of the Biotechnology, Biosafety and Biosecurity Policy of Guyana is presented in Figure 3. The competent body shall be the **National Biosafety Authority** of Guyana (NBA), a semi-autonomous agency that shall be set up initially as a semi-autonomous body within the EPA. All appointments to the National Biosafety Authority shall be for a five-year term. The President's designate or the Presidential Adviser on Sustainable Development shall appoint members. The composition of the NBA shall reflect the present representation on the

NCC of the NBF Project. However, efforts must be made to include persons from the private sector. Members of the NBA shall include expertise in human and veterinary medicine, agriculture, plant breeding, microbiology, molecular biology, environmental protection, food production and processing, social science, economics and military science. The NBA will provide oversight to the Guyana Biotechnology Corporation (GBC), which shall be legitimised by an act of Parliament. The GBC shall be established at either Institute of Applied Science and Technology (IAST) or NARI after an assessment of institutional mandate and ease of alignment.

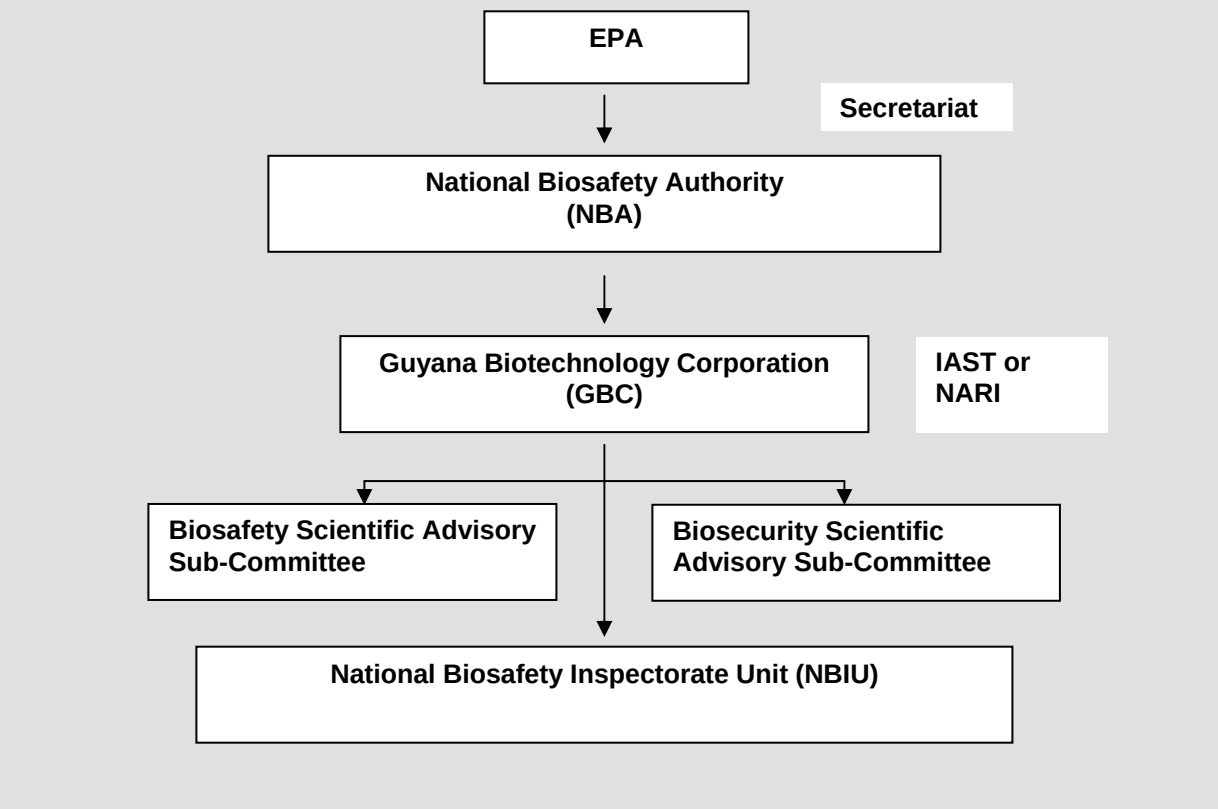

Figure 3. Institutional Framework for the administration of the Biotechnology, Biosafety and Biosecurity Policy of Guyana.

The mission of the Authority must be based on the principles outlined earlier. The functions of the NBA shall be as follows:

- Coordinate research and development;
- Receive and process applications;
- Ensure public education and awareness on relevant issues pertaining to biotechnology, biosafety and biosecurity in a timely manner;
- Promote accumulation of knowledge, dissemination of information, create active dialogue between researchers and other specialists, politicians and other citizens;
- Draw up, implement and monitor appropriate occupational safety protocols at work places where biotechnology procedures are used or products handled;

- Advise on appropriate labelling of GMOs in feedstuffs and feeds sold in or imported to or through Guyana;
- Defend the image of the country in the field of biotechnology, biosafety and biosecurity;
- Create and maintain a bio-informatics database as well as an information and promotion website; and
- Representing the biotechnology industry overseas.

The GBC shall regulate the biotechnology industry under the appropriate national legislation and with respect to the international Protocols and Conventions to which Guyana subscribe. The GBC shall be answerable to the NBA. There shall be within the NBA, a National Biosafety Inspectorate Unit (NBIU), to carry out inspection activities. Initially, the NBIU shall be set up within the Guyana National Bureau of Standards (GNBS) but shall come under the purview of the NBA at the time of it coming into being. Greater institutional coordination is desirable in view of the opportunities and risks involved in biotechnology. The primary function of the Inspectorate would be to monitor fundamentally important and new applications, and conduct supervision. It should have a special responsibility to ensure that ethical assessments in connection with biotechnology issues are considered.

Regulation and administration by the NBA, and assisted by NBIU, and on occasions by the GBC, in collaboration with relevant state agencies, shall include, but not limited to the following:

- Agricultural law enforcement, crops and livestock disease control, registration of livestock importation and agricultural products;
- Environmental impact assessment and food safety review functions;
- Industrial practices review and import/export management functions;
- Occupational food safety standards review functions;
- Customs and excise functions with respect to GMOs;
- Border control and forensic science with respect to GMOs;
- Policy integration and institutional coordination functions; and
- Marine research management, stock assessment and impact assessment processes.

The NBA will develop a regulatory framework for GMOs. One of the key elements to consider when developing the regulatory framework is public involvement in the decision-making processes. Once a regulatory framework for GMOs is in place, requests for commercial approval of individual GMOs can be processed. The decision-making process needs to provide an entry point for consultation with the public, and provisions for taking into account feedback from groups of the public. That entry point could take a number of forms such as a committee containing representatives of the public, feedback through a focal point, or a formal process of submission of a decision to the public. In addition, there has to be a recourse procedure for appeal of a decision, as well as access to justice.

The decision-making process includes a risk assessment (see Annex 3), which according to Codex Alimentarius, is defined as a scientifically based process consisting of the following steps:

(i) hazard identification;
(ii) hazard characterisation;
(iii) exposure assessment; and
(iv) risk characterisation.

After individual GM products have been approved, the regulatory framework may include provisions for post-release monitoring of the impacts of GMOs, where feedback from the public, especially those in rural areas where they are produced, would be of particular importance.

All GMOs must be identified and labelled such that they can be traced. Products thereof must also be labelled stating the fact that there is evidence of the presence of GMOs in the product. Labelling is also required to indicate that the presence of GMOs in a product cannot be excluded, if this were the case. Further, the label must forewarn of any allergies, reactions or other side effects that the GMOs or products thereof may cause. The GNBS in collaboration with the GA/FDD can convene a select committee to draft and have ratified, labelling standards for GMOs in Guyana.

This policy proposes that the Organisation for Economic Cooperation and Development (OECD) system of unique identifiers for transgenic plants be used when referring to GE crops. A unique nine-digit letter and number code is given to each new transgenic plant that is approved for commercial use and becomes its name worldwide. So, for instance, any unique variety of maize developed to be resistant to insect pests has a unique identifier of MON-OO810-6 (Monsanto) or cotton denoted by DD-O1951A (DuPont). OECD countries are already using the system. The EU recently adopted it as its system for generating unique identifiers and it has been recognised as a mechanism for unique identification to be used within the context of the Cartagena Protocol. The OECD is now considering how the identifier tool can be extended beyond crops to micro-organisms and animals.

2.8.2 Separation of biotechnology development and biosafety regulation functions

A regulatory agency cannot and must not be the same to promote technology development and entrepreneurship in biotechnology. To ensure the separation of regulatory functions from biotechnology enterprise development functions, an alternate institutional framework is proposed in Figure 4.

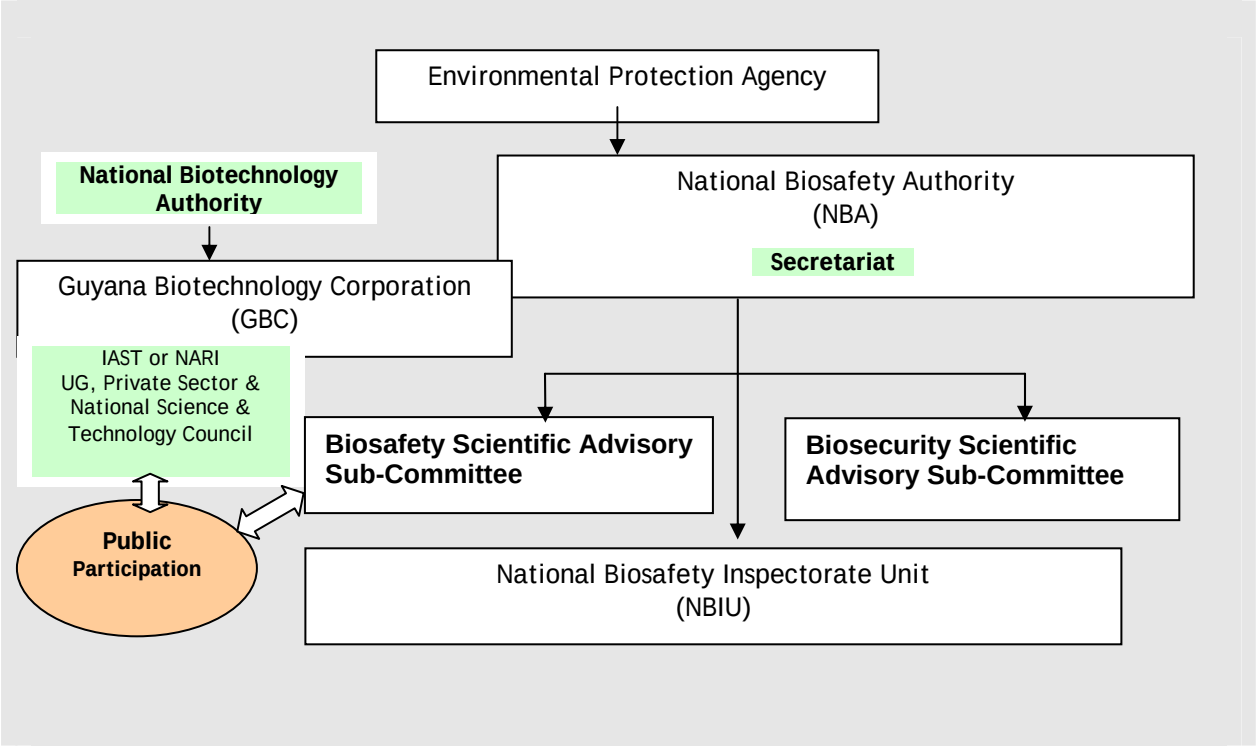

Figure 4. Alternate Institutional Framework for the administration of the Biotechnology, Biosafety and Biosecurity Policy of Guyana.

3. SYSTEM TO HANDLE NOTIFICATION OR REQUESTS FOR AUTHORIZATION

3.1 OVERVIEW OF SYSTEM

Under a new Biosafety bill, all notifications and request for handling authorizations relating to biotechnology related research, innovation, enterprise development, GMO trade, transboundary movement, among others, shall be made through application to the EPA. The EPA shall then submit the full complement of the application and all related documentation to the NBA secretariat. The secretariat shall have full responsibility for processing, review and recommendations for the issuance of a **certificate of approval or authorization** with **authorized seal** as prescribed by the Biosafety Bill. The institutional structure for the process is provided in Figure 5 below.

The following categorizations of the various applications shall be considered:

1. Contained use.
2. Deliberate release into the environment.
3. Placement on the market.
4. Food.

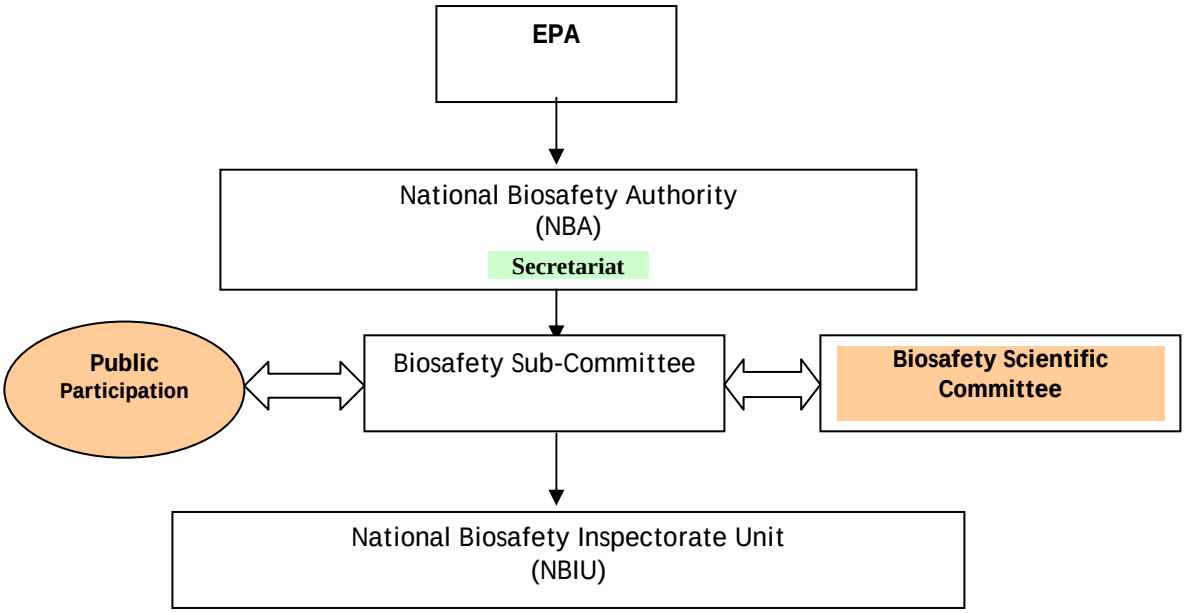

Figure 5. Proposed system to handle notification or requests for biotechnology and GMO-related authorizations.

Following receipt of the application from the EPA, the NBA secretariat shall convene the Biosafety Scientific Committee within seven (7) days for review of the application. The Biosafety Scientific

Committee shall be required to review and provide professional scientific advisory/guidance report within sixty (60) days. Where relevant, the National Biotechnology & Biosafety Inspectorate Unit (NBIU) shall be required to conduct all relevant inspections, if any, on physical infrastructure and related biodiversity, environmental and health implications of the application.

On completion of such an inspection, a biosafety inspection report as detailed by the relevant schedule to the Biosafety Bill shall be presented to the NBA secretariat. Such inspections shall be conducted within a reasonable time to permit the relevant review by the Biosafety Scientific Committee. On receipt of the Biosafety Scientific Committee's report, the Biosafety Sub-Committee shall be convened for a decision on the application within fourteen (14) days. The NBA Secretariat shall transmit the decision to the EPA for the issuance or denial of the certificate of approval or authorization, to meet the ninety (90) days requirement stipulated by the Protocol. Where there is rejection, the applicant shall be afforded an opportunity for review with relevant additional data or documentation as may be required.

3.2 CONTAINED USE OF GMOS

For the purposes of this framework, contained use shall require the following:

- Expert opinion from the Biosafety Scientific Committee;
- Fulfilment of all biosafety levels 1, 2, 3 and 4 requirements;
- Categorization of the biosafety level;
- Compliance with Occupational Safety and Health Act;
- EIA;
- Risk assessment statement including details as per schedule in Biosafety Bill;
- Inspection of the premises on which contained use is to be fulfilled;
- Detailed characteristics of the GMO as per schedule in Biosafety Bill; and
- Specified containment measures.

3.3 DELIBERATE RELEASE INTO THE ENVIRONMENT

Authorizations for the deliberate release into the environment shall require the following:

- Detailed characteristics of the GMO as per schedule in Biosafety Bill;
- Compliance with all environmental management guidelines under the EPA Act;
- Expert opinion from the Biosafety Scientific Advisory Committee;
- Compliance with Occupational Safety and Health Act;
- EIA;
- Risk assessment statement (see Annex 3) including details as per schedule in Biosafety Bill; and

- Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity (see Annexes 4a and 4b) with particular emphasis on the national endemic species and keystone species.

3.4 PLACEMENT ON THE MARKET

Authorizations for the placement of GMOs and their derivatives on the market shall require the following:

- Detailed characteristics of the GMO as per schedule in Biosafety Bill;
- Detailed characteristics of the GMO derivative and related bioprocess technologies from which it is derived;
- HACCP;
- Compliance with Food Act;
- Compliance with Food and Drugs Act;
- Compliance with Codex Alimentarius guidelines;
- Compliance with Customs Act (Amendment) 2005 as appropriately harmonized to the Biosafety Bill;
- Expert opinion from the Biosafety Scientific Advisory Committee;
- Compliance with Occupational Safety and Health Act;
- EIA; and
- Risk assessment statement including details as per schedule in Biosafety Bill.

3.5 FOOD

Authorizations for the use of GMOs or their derivatives as food shall require the following:

- Detailed characteristics of the GMO as per schedule in Biosafety Bill;
- Detailed characteristics of the GMO derivative to be used as food, food additive, food ingredient, food processing aid and related bioprocess technologies from which it is derived;
- HACCP;
- Compliance with Food Act;
- Compliance with Food and Drugs Act;
- Compliance with Codex Alimentarius guidelines;
- Compliance with Customs Act (Amendment) 2005 as appropriately harmonized to the Biosafety Bill;
- Expert opinion from the Biosafety Scientific Advisory Committee;
- Compliance with Occupational Safety and Health Act;
- EIA;
- Microbial risk assessment where relevant; and

- Risk assessment statement including allergenicity and other details as per schedule in Biosafety Bill.

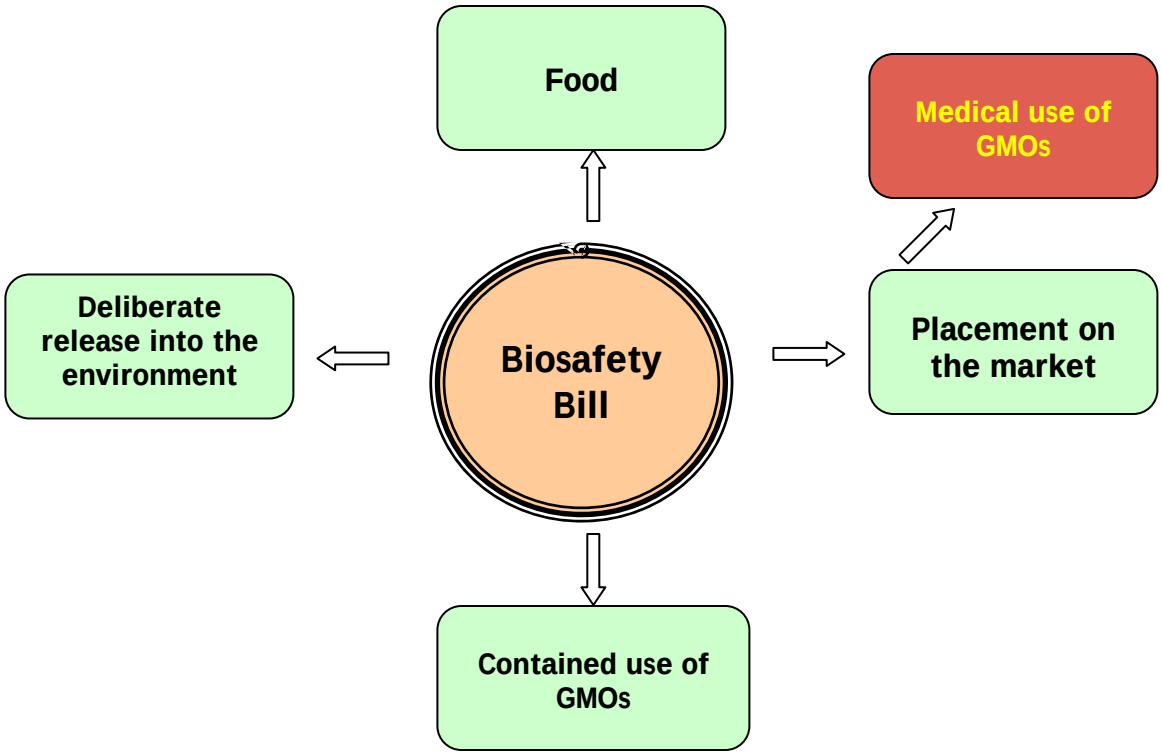

Figure 6. The scope of the National Biosafety Regulatory regime.

Annex 11 presents a best practice flowchart guide for safety assessment of GM food.

In consideration of the human health aspects in relation to GM/LM foods or derivatives there from, the following categories of human health testing shall be employed[18]:

1. Health-effects assessment (general testing for potential hazards)

   - Mammalian testing;
   - Digestibility assessment;
   - Allergenicity testing; and
   - Homology with known food allergens and toxins.

2. Human safety assessment

   Food safety aspects:

[18] US National Research Council Committee on genetically modified pest-protected plants report (2002).

- Compositional analysis;
- Nutritional assessment (concentrations and effects on bioavailability);
- Unexpected or unanticipated effects;
- Dietary exposure assessment;
- Determination of substantial equivalence; and
- Animal-feed consideration.

Non-food safety:

- Worker exposure; and
- Bystander exposure (for example, via pollen).

Other specific procedures shall include the following:

1. Recombinant DNA
   a. For projects involving the use of recombinant DNA[19], a research biosafety protocol must be submitted to the Biosafety Sub-Committee for review.
   b. All approved experiments employing recombinant DNA technology must be registered with the Biosafety Scientific Advisory Committee.
   c. The Principal Investigator shall be responsible for complying fully with guidelines in conducting any recombinant DNA research.

2. Chemical carcinogens
   a. A research protocol form involving the use of regulated carcinogens must be submitted to the Biosafety Scientific Advisory Committee for review and approval.
   b. Investigators shall be required to file a safety plan for use of the regulated carcinogens.

3. Infectious disease agents
   a. Any experiments or bio-assays involving cells, tissues or body fluids obtained from humans or animals known to contain, or suspected of harbouring, infectious disease agents are to be handled and disposed of in accordance with internationally accepted standards.
   b. The Biosafety Scientific Advisory Committee must approve experiments involving animals that are carriers of infectious agents.

4. Blood borne pathogens exposure control
   a. The Biosafety Scientific Advisory Committee shall provide education and exposure-prevention guidelines to persons who may be exposed to blood borne pathogens.
   b. Human blood, primate blood and/or body fluids from primates, and clinical samples, shall not be used unless approved by the Biosafety Scientific Advisory Committee.

[19] For more information, read Snow, *et al*. (2003). Genetically engineered organisms and the environment: Current status and recommendations. Ecological Society of America Position Paper. 55p.

3.6 CURRENT SITUATION

The nation has not been specifically confronted with a specific request so far. However, preliminary surveys indicate the presence of a few GMO seeds. These may have been routinely imported for the improved seed characteristics without careful consideration of the methods by which the seeds were produced. Clearly, lack of an adequate system and knowledge is accountable. A variety of processed foods on the local market may potentially be derived from possible GMOs. One of the distinct cases is vegetarian cheese bioprocessed from GM-derived chymosin. The sources of bakers and brewers yeast in the manufacturing industries have not been adequately ascertained. In essence, despite the inclusion of GMOs in the EP Act (albeit inadequately) as well as in the Customs (Amendment) Act 2005, there is no clearly defined regulatory mechanism for the identification and monitoring of GMOs and related derivatives and or products in Guyana. On-going surveys indicate a possible lack of adequate knowledge across a wide spectrum of the society.

3.7 THE PROPOSED BIOSAFETY REGULATORY SYSTEM

Under the proposed new system as illustrated in Figure 5, all requisite applications for certificates of approval or authorization shall be handled by the NBA under the new Biosafety Bill with inter-agency oversight by the EPA. The NBA shall be designated the National Competent Authority, on all matters relating to GMOs and related derivatives and products in Guyana.

The secretariat shall have full responsibility for processing, review and recommendations for the issuance of a **certificate of approval or authorization** with **authorized seal** as prescribed by the Biosafety Bill.

3.7.1 Composition of the NBA

The NBA shall be an independent regulatory agency by law constituted as a multisectoral body comprising the following:

1. Chairman
2. Vice-Chairman
3. Two Representatives of the EPA drawn from:
    a. The Division of Environmental Management of the EPA
    b. The Division of Natural Resource Management of the EPA
4. Director of Food and Drugs Department of the Ministry of Health or legal designate
5. Director of NARI or legal designate
6. Director of IAST or legal designate
7. Commissioner of Forests or legal designate
8. Chairman of the Pesticides and Toxic Chemicals Control Board or legal designate

9. Chairman of the National Commission of Codex Alimentarius or legal designate
10. Representative of the Private Sector Commission
11. Representative of the Amerindian Community
12. Representative of the University of Guyana
13. Representative of the Farmers' Association
14. Representative of the Guyana Consumers Association
15. Representative of the National Science and Technology Research Council
16. Representative of the Guyana Biotechnology Corporation
17. Representative of the Religious community
18. Representative of the Minister of Industry, Commerce and Tourism
19. Representative of the Minister of Foreign Trade and International Cooperation
20. Representative of the Attorney-General and Minister of Legal Affairs
21. Representative of the Lands and Surveys Commission
22. Representative of any other most relevant agency [e.g. Customs division of GRA; Joint Services].

3.7.2 Application for biosafety clearance

Applications shall be categorized according to the following and assigned identification numbers for administrative tracking:

1. Contained use.
2. Deliberate release into the environment.
3. Placement on the market.
4. Food.
5. Medical use.

The administrative procedure relating to the processing of all applications shall require the following:

1. The NBA secretariat shall convene the Biosafety Scientific Advisory Committee within seven (7) days for review of the application.
2. The Biosafety Advisory Scientific Committee shall be required to review and provide professional scientific advisory/guidance report within sixty (60) days.
3. The National Biosafety Inspectorate Unit (NBIU) shall be required to conduct all relevant inspections, if any, on physical infrastructure and related biodiversity, environmental and health implications of the application.
4. The NBA shall convene the National Biosafety Scientific Advisory Committee.
5. The National Biosafety Scientific Advisory Committee shall deliver a preliminary opinion.
6. The NBA shall convene a public consultation of all relevant stakeholders as identified in the schedule to the Biosafety Bill to discuss the preliminary Opinion of the Biosafety Scientific Advisory Committee and obtain a **Public Opinion.**

7. The National Biosafety Scientific Advisory Committee shall consider all reports including the **Public Opinion** from the public consultation on the **sound scientific merits** and a decision will then be made on authorization within ninety (90) days of the initial application as stipulated by the Protocol.

The process shall be guided by the following:

- National Biotechnology Guidelines;
- National Biosafety Guidelines;
- Administrative Guidelines for Biosafety applications; and
- Biotechnology and Biosafety Risk Assessment Guidelines [as per sample in Box 7].

In the case of import and export of GMOs and their derivative products, specific national entry and exit points shall be as designated in the Biosafety Bill.

Box 7. Sample risk assessment template to guide applications for LM or GM Plants.

Regulations for the Deliberate Release of GM Higher Plants of the UK
General information

1. The name and address of the applicant.
2. The title of the project.

Information relating to the parental organism

3. The full name of the plant: family, genus, species, subspecies, cultivar.
4. Information on the reproduction of the plant: mode, generation time and sexual compatibility with other cultivated or wild plant species.
5. Information on the survivability of the plant: survival structures, dormancy, etc.
6. Information concerning dissemination of plant: means, extent and factors affecting dissemination.
7. The geographic distribution of the plant.
8. If the plant species is not normally grown in Member States, describe the natural habitat.
9. Information on any significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including toxicity to humans, animals and other organisms.

Information relating to the genetic modification

10. A description of methods used for genetic modification.
11. The nature and source of the vector used.
12. The size, function and donor organism(s) of each DNA sequence intended for insertion.

Information relating to the genetically modified plant

13. A description of the trait(s) and characteristics of the GM plant which have been modified.
14. Information on sequences inserted or deleted: size/structure, copy number of insert, information on any vector sequences or foreign DNA remaining in the GM plant. The size/function of any deleted regions. Cellular location of insertion (eg. chromosomal, mitochondria, chloroplast, etc.).
15. Information on the expression of the insert: expression and parts of the plant where expressed.
16. How does the GM plant differ from the recipient plant in mode/rate of reproduction, dissemination, survivability?
17. The genetic stability of the insert.
18. The potential for transfer of genetic material from the GM plants to other organisms.
19. Information on any toxic/harmful effects on human health and the environment arising from the genetic modification.
20. The mechanism of interaction between the GM plants and target organisms.
21. Any potential significant interactions with non-target organisms.
22. A description of detection and identification techniques for the genetically modified plants.

Information about previous releases of the GM plants

23. Information relating to the site of release.
24. The location and size of the release site or sites.
25. A description of the release site ecosystem, including climate, flora and fauna.
26. Details of any sexually compatible wild relatives or cultivated plants present at the release sites.
27. The proximity of the release sites to officially recognized biotopes or protected areas.

Information relating to the release

28. The purpose of the release.
29. The foreseen dates and duration of the release.
30. The method by which the GM plants will be released.
31. The method for preparing and managing the release site, prior to, during, and after the release.
32. The approximate number of GM plants (or plants per m^2) to be released.

Information on the control, monitoring, post-release plans and waste treatment plans

33. A description of any precautions to minimize or prevent pollen or seed dispersal from the GM plant.
34. A description of the methods for post-release treatment of the site or sites.
35. A description of post-release treatment methods for the GM plant material including wastes.
36. A description of monitoring plans and techniques.
37. A description of any emergency plans.

Information on potential environmental impact of the release of the genetically modified plants

38. The likelihood of any GM plant becoming more persistent or invasive than recipient plants.
39. Any selective advantage or disadvantage conferred to other sexually compatible plant species, which may result from genetic transfer from the genetically modified plant.
40. Potential environmental impact of the interaction between the GM plant and target organisms.
41. Any possible environmental impact resulting from potential interactions with non-target organisms.

4. MONITORING AND ENFORCEMENT

4.1 MONITORING

Monitoring and enforcement is critical in ensuring the effectiveness of any regulatory regime. Although there are no such systems in place presently, the proposed system envisages a surveillance protocol under the aegis of the National Biosafety Inspectorate Unit (NBIU). Specific requirements for monitoring shall be guided by a case-by-case approach to the relative risks expected from the execution of each particular application. The applicant shall also ensure its own monitoring procedures as detailed in its application on biosafety management procedures.

The new administrative mechanism on biosafety envisages the establishment of a National Biosafety Inspectorate Unit. In accordance with the proposed Biosafety Act, the functions of the Biosafety Inspectorate, in collaboration with inter-agency institutions, shall be, but not restricted to, the following:

i. Agricultural law enforcement, crops and livestock disease control, registration of livestock importation and agricultural products;
ii. Environmental impact assessment and food safety review functions;
iii. Industrial practices review and import/export management functions;
iv. Occupational safety and health standards related to biosafety ;
v. Food safety standards related to biosafety;
vi. Drug safety standards related to biosafety;
vii. Medical biotechnology interventions related to biosafety;
viii. Customs and excise functions with respect to GMOs;
ix. Border control and forensic science with respect to GMOs;
x. Inspection and enforcement of institutional coordination functions related to biosafety; and
xi. Marine research management, stock assessment and impact assessment processes.

Biosafety inspectors shall be the monitoring and enforcement officers. They may include officers of other regulatory and law enforcement agencies so designated by the NBA. These Biosafety Inspectors are to be appointed by the Head of the Secretariat on the recommendations of the Board of the NBA and shall receive an instrument of appointment together with a prescribed identification badge. The Powers of Biosafety Inspectors as recommended in the draft Biosafety Bill are:

i. Confiscate any suspected illegal GMO or products thereof;
ii. Serve cessation orders on biotechnology activities deemed risky or unapproved; and
iii. Request for inspection from anyone using GMOs the certificate of authorization.

4.2 ENFORCEMENT AND STRATEGIES FOR EFFECTIVENESS

The overall responsibility for enforcement shall reside with the National Biosafety Inspectorate Unit (NBIU) under the direct supervision of the NBA with inter-agency cooperation with the EPA and the Law enforcement agencies – the Guyana Police and Defence Forces when necessary.

The NBA, as established under the Biosafety Bill, shall have executive authority over the entire system of monitoring, and enforcement. Under the Biosafety Bill, the NBA shall also have the overall responsibility for monitoring risk management procedures involving all biotechnology and biosafety regulated products and materials.

Enforcement of food safety requirements shall be delegated to a Food and Drugs Department with an enhanced capacity for GM foods analysis as per the Codex Alimentarius **Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants.**

4.3 INTER-AGENCY COORDINATION

The NBA shall seek to maintain an inter-agency cooperative oversight in all matters relating to the monitoring and enforcement of all regulations under the Biosafety Bill. Figure 7 presents a schematic overview of institutions involved in environmental enforcement and natural resources management. It is clear that the process is complex and inter-related.

Annex 10 presents the institution that would have an important role to play with respect to the NBA, and the areas of focus of the work of the NBA through its Secretariat.

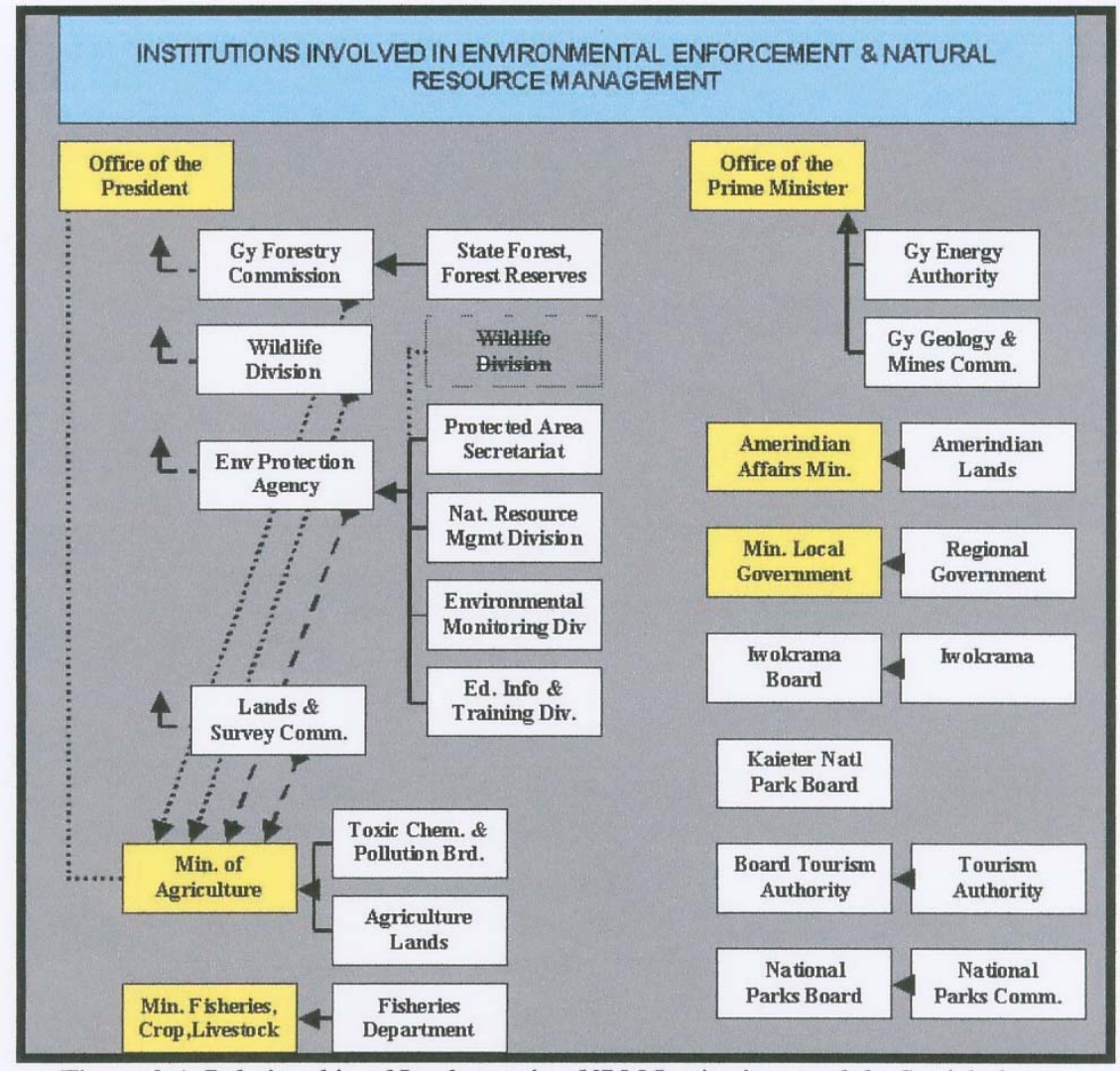

Figure 7. Environmental enforcement and natural resource management institutions of Guyana. (Source: USAID/Guyana 2003,)

5. MECHANISMS FOR PUBLIC AWARENESS, EDUCATION, ACCESS TO INFORMATION AND PARTICIPATION

5.1 CURRENT SITUATION

Within the scope of the EP Act, all EIA procedures require mandatory public participation. The applicant is required to adhere to the following process for public scrutiny following public notification by the EPA:

- Submission of the applicable prescribed fees;
- Project summary which shall include information on:
    - The site, design and the size of the project;
    - Possible effects on the environment;
    - The duration of the project;
    - A non-technical explanation of the project;
- Before an EIA is conducted, the EPA publishes (at the developer's cost) a notice in at least one of the daily newspapers of the project and makes available to the public all the project-related information as stipulated above;
- Members of the public have 28 days from the date of the publication to make written submissions on questions and matters they wish to have considered in an EIA;
- The EPA then consults with the independent EIA expert for the project and sets the terms and scope taking into account the public submissions;
- Following the EIA process, an EIA report and an environmental impact statement (EIS) is submitted to the EPA;
- The EIA report and EIS are then made public by the EPA;
- Public hearings are conducted on the EIA report and EIS;
- The EIA report and EIS are then submitted to the Environmental Assessment Board (EAB) for review and ascertainment of adequacy;
- The EAB recommends approval or rejection to the EPA; and
- An environmental permit is then issued or denied on the basis of the EAB recommendation.

Generally, the EPA conducts public awareness programmes on environmental issues through the radio, television and print media. It also produces an annual calendar depicting different environmental issues yearly for wide distribution. Occasionally, depending on the availability of resources, debating and essay competitions for primary and secondary schools have been organized in collaboration with the private sector. A weekly column of the EPA in one of the national daily newspapers provides short essays on a wide range of topical issues on the environment.

A flowchart of the present system for environmental permits is provided in Annex 2.

5.2 METHODS TO ACHIEVE BIOTECHNOLOGY AND BIOSAFETY PUBLIC AWARENESS

In elaborating on the present processes engaged by the EPA in public awareness, the NBF proposes to set in motion an action framework developed from the results of the 1st National Biosafety workshop on public awareness, education and participation. The framework identifies the information and communication modes and relevant target groups as follows:

5.2.1 Information and Communication modes

1. Use of the Media
   - Print:
     - Newspaper articles;
     - Flyers; and
     - Posters.
   - Electronic (TV and Radio):
     - Jingles with popular local lyrics;
     - Infomercials;
     - talk shows;
     - websites; and
     - email circulars.

2. Outreach Programmes
   - Seminars;
   - Workshops;
   - Meetings with interest groups, e.g. farmers;
   - Bill boards;
   - Trade fairs; and
   - Field trips.

3. Target Groups for general public education and awareness:
   - Decision makers;
   - Households;
   - Schools – quiz, essay competitions, school talks;
   - Religious bodies;
   - Professional bodies;
   - Importers; and
   - Consumers.

4. Public education on biotechnology and biosafety target groups

- Target Groups:
    - Schools;
    - Educational Institutions;
    - Community Leaders;
    - Communities;
    - Consumers;
    - Producers;
    - Policy Makers;
    - Seed Importers; and
    - Importers – Canned Products.

- Media:
    - Public Meetings;
    - Group Meetings;
    - Community Leaders Meetings;
    - NDCs, RDCs and RECs;
    - Foot Soldiers;
    - CHW;
    - Agriculture Extension Workers;
    - NDDP – AI Personnel;
    - Guyana Consumers Association;
    - TV;
    - Radio;
    - Print; and
    - Internet.

- Workshops/Seminars

- Capacity Building:
    - Technical Training;
    - Trainer of Trainers Training; and
    - Simulation of Biotechnology Process.

- Information must be balanced.

5.2.2 Key Stakeholders in Public Participation Processes

- Government Agencies:
  a. Ministry of Agriculture:
    - NARI;
    - GRDB;

- Pesticides and Toxic Chemicals Board;
- New GMC; and
- Plant Quarantine.

b. Ministry of Fisheries, Crops & Livestock:
   - National Dairy Development Programme; and
   - Guyana Dairy Project (Sophia).

c. Ministry of Home Affairs:
   - GDF (Coast Guard, etc.); and
   - Guyana Police Force.

d. Ministry of Health:
   - Food & Drugs; and
   - Medical Labs.

e. Ministry of Finance:
   - Customs & Excise Dept. and Immigration; and
   - Bureau of Statistics.

f. Ministry of Legal Affairs:
   - DPP Office.

g. Ministry of Education:
   - NCERD; and
   - Schools.

h. Ministry of Amerindian Affairs

i. Ministry of Culture, Youth & Sport

j. Ministry of Local Government

k. Ministry of Foreign Affairs

l. Ministry of Foreign Trade & International Cooperation

m. Ministry of Tourism, Industry & Commerce:
   - Bureau of Standards.

- Other Agencies:
   - GGMC;

- GFC;
- Lands & Surveys Commission;
- EPA; and
- Guyana Tourism Authority.

- Non-Governmental Organisations:
  - Iwokrama;
  - Conservation International;
  - Cattle Farmers Association;
  - Smithsonian Association;
  - Religious Bodies;
  - Bar Association;
  - Women's Groups; and
  - Amerindian Groups (APA, etc.).

- Private Sector:
  - PSC;
  - GuySuCo;
  - Seafoods;
  - Stockfeed;
  - Bakeries;
  - Breweries;
  - THAG;
  - Mining Companies;
  - GMA;
  - GCCI; and
  - GWI.

- Decision Makers:
  - Parliamentary Groups;
  - Cabinet Subgroups; and
  - Nat. Res., Energy, Mining, Trade.

- Research & Education:
  - CARDI;
  - GSA;
  - UG;
  - IAST; and
  - IDS.

- Media:
  - Newspapers;

- Radio;
- TV; and
- Internet.

5.3 BIOTECHNOLOGY AND BIOSAFETY EDUCATION AND AWARENESS SUB-COMMITTEE

Under the proposed guidance, there shall be the establishment of a Biotechnology and Biosafety Education and Awareness Sub-committee consisting of key stakeholder representatives of no more than seven (7) persons. At least half of such members would be required to possess the requisite minimum professional qualifications in areas relating to biotechnology and biosafety as well as general environmental education.

The Biotechnology and Biosafety Education and Awareness Sub-committee would be coordinated by the NBA Secretariat, and the latter shall be required to submit recommendations emanating from their deliberations to the Board of the NBA for ratification and implementation by the relevant designated officer of the Secretariat.

5.4 REGIONAL BIOSAFETY DATABASE

The CSME seeks to integrate the economies of the CARICOM countries. With its coming into force in January 2006, biosafety regulatory processes in the Region need to be harmonized. In this regard, the processes commenced through a workshop on Regional BCH will be pursued. A dual approach to biosafety databasing is therefore advocated by this NBF. Guyana shall maintain its own national BCH as well as participate fully in a Regional BCH databasing system.

The regional BCH will ensure:

(i) a harmonious system of information deposition and retrieval by all participating member states;
(ii) facilitation of biosafety knowledge leveraging in an otherwise unevenly distributed human resource capacity among a community of nations;
(iii) facilitation of rapid acquisition of prior decisions in member countries;
(iv) facilitation of sourcing relevant biosafety expertise where and when relevant;
(v) harmonization of systems of risk assessment; and
(vi) harmonization of legal issues within the framework of the Caribbean Court of Justice (CCJ) as the highest judicial forum within CARICOM in cases of appeals and liability and redress relating to the Protocol.

5.5 NATIONAL BIOSAFETY DATABASE – NATIONAL BIOSAFETY CLEARING-HOUSE (BCH)

As part of the NBF process, a series of surveys was conducted as summarized in Table 4 below. Data gleaned from these surveys are in the process of final scrutiny and inputting to the national BCH database.

Table 4. Summary of the surveys conducted as part of the Guyana NBF process.

Survey on the State of General Science & Technology and Related Expertise in Guyana.
Survey on the Existing Uses of Biotechnology, Arrangements for Safe Use and Related Expertise in Guyana.
Review and Assessment of Existing Legislation that may impact on Modern Biotechnology and Related Expertise in Guyana.
Survey on the Existing National, Bilateral and Multi-lateral Capacity Building, Research and Development, and Biotechnology application initiatives in Guyana.
Survey on the Existing National Biosafety Frameworks in countries of the Latin America and Caribbean sub-region.
Review and Assessment of Existing Mechanisms for Harmonization of Biosafety-related Legislation in Guyana.
Survey of the Existence of National or Regional Risk Assessment/Management Capacities and Recommendations for Mechanisms for Harmonization in Countries of Latin America and Caribbean sub-region.
Survey on the Existence, Extent and Impact of Release of LMOs and related Commercial Products in Guyana.
Preparation of a Draft Biotechnology, Biosafety and Biosecurity Policy for Guyana.

The basic elements of the national input to the regional BCH shall be:

- Brief introduction/overview of the structure of the national BCH.
- National contacts:
    i. National Focal points;

    ii. National point of contact for receiving notifications regarding unintentional transboundary movements of LMOs/GMOs;
    iii. BCH national focal points;
    iv. Competent national authorities; and
    v. National databases.
- Laws and regulations:
    i. National laws, regulations and guidelines; and
    ii. Bilateral, regional and multilateral agreements.
- Decisions and declarations pertaining to LMOs/GMOs:
    i. Decisions on LMOs/GMOs under Advance Informed Agreement (AIA) procedure;
    ii. Decisions on LMOs/GMOs for direct use as food or feed, or for processing (LMOs-FFP/GMOs/FFP); and
    iii. Other decisions and declarations.
- Risk assessments (see Box 5).
- Unique identifications.
- Capacity-building:
    i. Capacity-building opportunities;
    ii. Capacity-building projects and initiatives; and
    iii. Capacity-building needs and priorities.
- Roster of national experts.
- Other resources:
    i. Relevant sites and tools;
    ii. Bibliographic information;
    iii. Downloadable files; and
    iv. Frequently asked questions.
- Basic information on how to use the national BCH site.

The national BCH is designed to be an invaluable tool for public access to information, awareness and education on all relevant biosafety issues. Hyperlinks will afford the public the opportunity to access comparative information in the Caribbean Region and within the global BCH central in the final analysis.

Box 5. Global prescribed common format for BCH database on risk assessment.
Risk assessment details
1. Country Taking Decision:
2. Title:
3. Contact details:
LMO information
4. Name and identity of the living modified organism:
5. Unique identification of the living modified organism:
6. Transformation event:
7. Introduced or Modified Traits:
8. Techniques used for modification:
9. Description of gene modification:
Characteristics of modification
10. Vector characteristics (Annex III.9(c)):
11. Insert or inserts (Annex III.9(d)):
Recipient organism or parental organisms (Annex III.9(a)):
12. Taxonomic name/status of recipient organism or parental organisms:
13. Common name of recipient organism or parental organisms:
14. Point of collection or acquisition of recipient or parental organisms:
15. Characteristics of recipient organism or parental organisms related to biosafety:
16. Centre(s) of origin of recipient organism or parental organisms:
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:
18. Habitats where the recipient organism or parental organisms may persist or proliferate:
Donor organism or organisms (Annex III. 9 (b)):
19. Taxonomic name/status of donor organism(s)
20. Common name of donor organism(s):

21. Point of collection or acquisition of donor organism(s):
22. Characteristics of donor organism(s) related to biosafety:
Intended use and receiving environment
23. Intended use of the LMO (Annex III. 9 (g)):
24. Receiving environment (Annex III. 9 (h)):
Risk assessment summary
25. Summary of risk assessment or environmental review:
26. Detection/Identification method of the LMO (Annex III. 9 (f)):
27. Evaluation of the likelihood of adverse effects (Annex III. 8 (b)):
28. Evaluation of the consequences (Annex III. 8 (c)):
29. Overall risk (Annex III. 8 (d)):
30. Recommendation (Annex III. 8 (e)):
31. Actions to address uncertainty regarding the level of risk (Annex III. 8 (f)):
Additional information
32. Availability of detailed risk assessment information:
33. Any other relevant information:
34. Attach document:
35. Notes:

5.6 BIOSAFETY INFORMATION AND COMMUNICATION STRATEGIES

Effective good practice mechanisms will be put in place to ensure the public is made well aware of the developments pertaining to biotechnology and related biosafety issues. Following a national consultation, some agreed guidelines for effective public awareness and education on all matters relating to biosafety in Guyana are provided in the section on **Methods to Achieve Biotechnology and Biosafety Public Awareness.**

5.6.1 Strategies for best-practice modalities for public awareness, education, access to information and participation in biosafety

Pursuant to the suggested **Methods to Achieve Biotechnology and Biosafety Public Awareness**, the NBA shall leverage relevant best practice mechanisms collated by the UNEP Biosafety Global Project in the publications on public participation and awareness as best within the local environment and public approach to issues. To this end, the methods identified by stakeholders and represented in this document should serve as a good background document for what is believed can be workable for a successful approach in Guyana

6. THE GUYANA NATIONAL BIOSAFETY FRAMEWORK DEVELOPMENT PROCESS

The National Biosafety Framework development process followed the standard guidance template provided by UNEP which consisted of the following **four sequential phases**:

- **Phase 0** - the vision of the project, design and establishment of institutional and project management structures;
- **Phase 1** - the gathering of baseline data/information following the instigation of surveys such as this one, and the documentation and storage of data (inventorization);
- **Phase 2** - the widening of the scope for identification of stakeholders, analysis of the baseline inventories, stakeholder consultations and training; and
- **Phase 3** - drafting of the National Biosafety Framework.

The working ethos of the process was that the National Biosafety Framework project was taking Guyana from a zero stage where national biosafety and biotechnology policies, biosafety laws and regulatory regimes were non-existent, to a stage where a draft national biosafety framework document with related draft biosafety legislation would have been prepared.

The five key components of the draft biosafety framework to be developed for Guyana were:

- Biosafety policy;
- Regulatory regime including appropriate biosafety laws;
- System to handle requests which would involve the establishment of administrative, risk assessment and management, and decision-making mechanisms;
- Follow-up actions involving monitoring, inspections and enforcement of biosafety guidelines and laws; and
- Public awareness and participation.

The composition of the National Coordinating Committee (Annex 1a) of the NBF project was based on a previously agreed stakeholder grouping.

ANNEXES

ANNEX 1a. NCC STAKEHOLDER CATEGORIES AND REPRESENTATIVES

NCC Membership Stakeholder Categories	Agencies/Institutions Represented	Remarks
National Government	▪ Ministry of Fisheries, Crops & Livestock ▪ Attorney-General's Chambers ▪ Ministry of Foreign Affairs ▪ Ministry of Foreign Trade & International Cooperation ▪ Ministry of Health ▪ Ministry of Tourism, Industry & Commerce ▪ Ministry of Education ▪ Ministry of Amerindian Affairs	Comprehensively covered.
Community-based organizations & NGOs	▪ Guyana Consumers' Association	Another Civil society group may need to be identified.
The Public Sector	▪ National Agricultural Research Institute ▪ Environmental Protection Agency ▪ Customs and Trade Administration ▪ Guyana National Bureau of Standards ▪ University of Guyana - Faculty of Agriculture & Forestry - Faculty of Health Sciences - Faculty of Natural Sciences ▪ Guyana Forestry Commission ▪ Pesticide and Toxic Chemical Control Board	Comprehensively covered.
The Private Sector	▪ Georgetown Chamber of Commerce and Industry ▪ Guyana Sugar Corporation ▪ Guyana Rice Development Board Guyana Marketing Corporation	May need to consider the umbrella Private Sector Commission.
Traditional and Spiritual Leaders		Needed but was not represented at this time.
Local Government		May be required.
Religious organizations		Needed but was deferred for an ethics working group at a much later date of NBF draft.

ANNEX 1b. GUYANA NATIONAL COORDINATING COMMITTEE – LIST OF MEMBERS

BAKSH, Jameel
Deputy Commissioner
Customs & Trade Administration
229 Main & Hope Streets
Georgetown

Phone: 225-4280
E-mail: Jajab@guyana.net.gy

BERNARD-BARRY, Adjua
Environmental Officer
Natural Resource Management Division
Environmental Protection Agency
IAST Building
University Campus
Turkeyen
Greater Georgetown

Phone: 222-5784 or 5785 ext. 41
Fax: 222-2442
E-mail: abernard@epaguyana.org

Succeeded by:
PITAMBER, Parmeshwari
Senior Environmental Officer
Natural Resource Management Division
Environmental Protection Agency
IAST Building
University Campus
Turkeyen
Greater Georgetown

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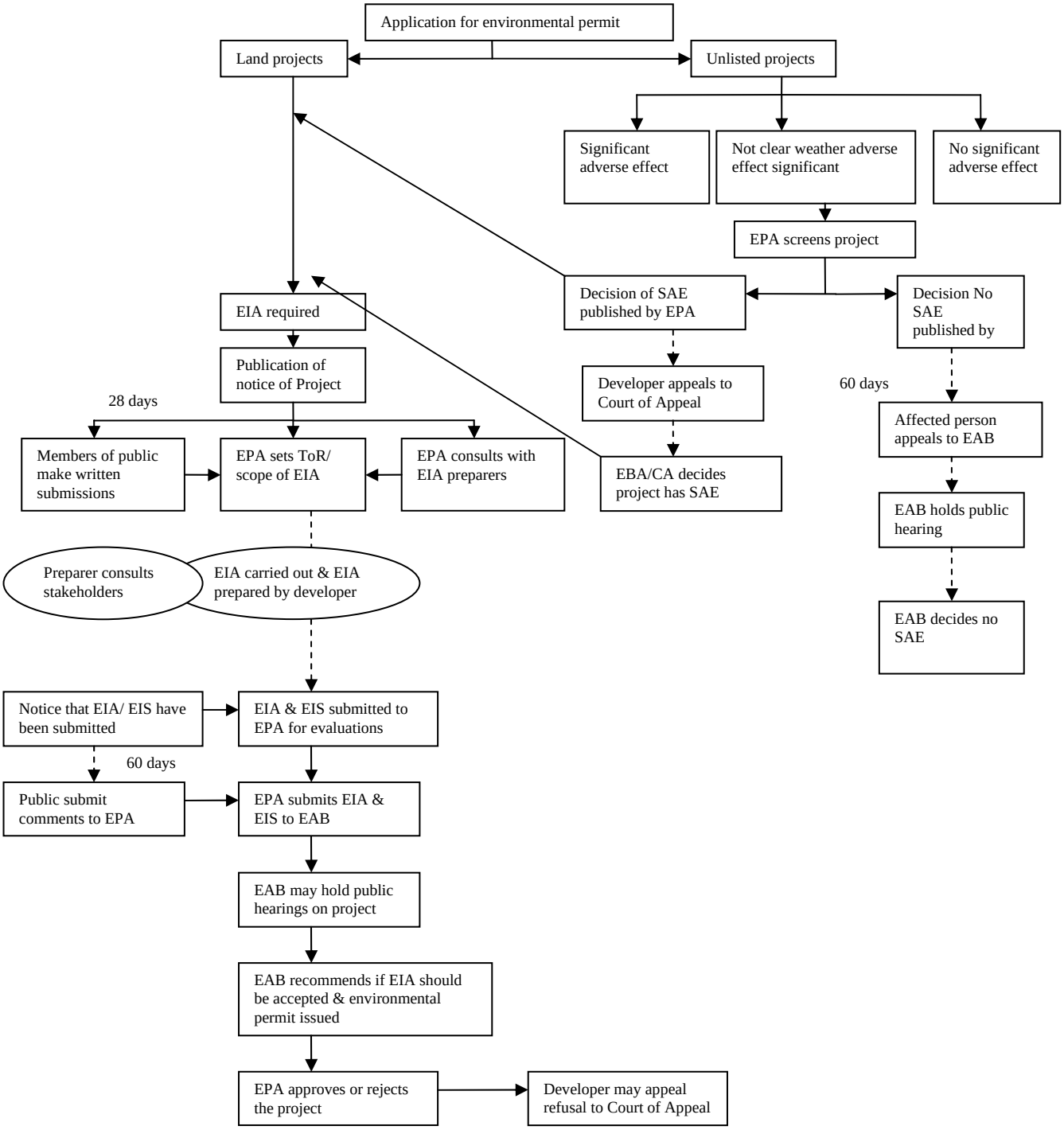
ANNEX 2. SCHEMATIC FLOWCHART OF THE PRESENT EPA SYSTEM FOR ENVIRONMENTAL PERMIT APPLICATIONS



ANNEX 3. SAMPLE RISK ASSESSMENT TEMPLATE TO BE MODIFIED FOR USE IN BIOSAFETY REGULATION GUIDELINES IN GUYANA

Questionnaire for Risk Assessment of Genetically Modified Organisms (GMOs) related to Agriculture (Adapted from the Association of Southeast Asian Nations Regional Guidelines).

A. CORE QUESTIONS

Species of organisms

1.	What is the species of GMO? Where relevant, give information on the strain, cultivar, etc.	A2
2.	Is the GMO capable of causing disease or other ill-health in humans, plants or animals? If so, what are the possible effects?	C2
3.	What is the origin of the inserted DNA? Does the inserted DNA come from an organism that causes disease or other ill-health in humans, plants or animals? If so, what are the possible effects?	[A3], B1

Eventual use of GMOs

1.	What is the aim of the proposal and the intended eventual use of the GMO?	General Information
2.	What are the advantages and disadvantages of the chosen strategy compared with other methods?	General Information

Location (for the release of GMO)

1.	Describe the size of the release, and, where relevant, the area of land to be used, and its location. Include a map, where relevant.	D5
2.	What are the reasons for the choice of location?	[D1], D5
3.	Describe in detail the relevant features of the physical environment, particularly those which may minimize or exacerbate any undesirable effects.	[D1], D5
4.	How close is the site to population centres, of agricultural activity, or the habitat of biota that might affect, or be affected by the release?	[D3], D5

Habitat and ecology

1	What is the natural habitat of the parent organism and its range?	A5
2.	Where was the parent organism originally isolated?	A2, A5
3.	What is the distribution of the parent organism in CARICOM/CSME member countries?	A5

4.	Is the parent organism already present at or near the site of the release? If so, provide available data on populations (for field trial).	A5
5.	Is the parent organism exotic to CARICOM/CSME member countries?	A2, A5
6.	Are there any known predators or parasites of the organism in CARICOM/CSME member countries? If so, describe.	C6
7.	Could the release of the GMO prejudice any beneficial function of the parent organism in the environment?	D4
8.	Describe any anticipated direct or indirect ecological effects of the release which are not covered in subsequent sections (B, C, D, etc.).	[C5, D8], D4

Genetics of the GMO

1.	What genetic modification has been made? Give a detailed description of the steps undertaken.	B1
2.	Does the GMO have a potentially unstable genotype?	B5
3.	To what extent is the genetic modification characterized? Provide data to show the extent of characterization.	B2
4.	What is the location of the inserted DNA in the final construct, and how many copies are present?	B2
5.	What markers or sequences will enable the GMO to be identified in the laboratory and under field conditions?	B2
6.	What type of vector was used in the transfer? Provide a description of the vector, showing the position of the inserted DNA and any other control sequences or markers in the vector.	B3
7.	Can the vector transfer to other hosts? If so, provide information on its host range.	B3, [C3]
8.	Is the recombinant vector present in the final construct? If not, how was it removed?	B4
9.	If no vector was involved: how was the DNA introduced and how many copies of the gene were inserted?	B3
10.	How does the modification change the phenotype of the organism? Present data to demonstrate the effect of the modification, including level of expression and regulation of the genetic insert. What secondary genetic effects may be anticipated?	General Information, C7, [C8]
11.	What intrinsic genetic features, if any, of the GMO regulate its survival in the environment if it is released? How stable are these features?	D1, B5
12.	What genetic changes, if any, have been included in the GMO to limit or eliminate its capacity to reproduce or transfer its genes to other organisms?	C5

Data from contained work and other studies on stability, survival and transfer

1.	On the basis of contained experiments, provide data on: i. the survival times of the GMO in habitats relevant to the release; ii. the growth rate (or generation time) of the parent organism and GMO in the ranges of environmental conditions characteristic for the place and date of release; and iii. the frequency of reversion or loss of the genetic change.	Supporting Data
2.	What is the capability of the GMO to disperse from the release area? What are the dispersal mechanisms in air, water and soil?	Supporting Data
3.	Can the parent organism form long-term survival structures such as seeds or spores?	Supporting Data
4.	Is there any evidence that the inserted genetic trait can be transferred to other organisms found at the release site and surrounding environment? If so: i) to what organisms and at what frequencies? List the species that have been tested for transfer and explain the rationale for this choice; ii) what transfer mechanisms are involved?; iii) what techniques have been used to demonstrate transfer?; and, iv) what are the possible adverse effects of the transfer?	Supporting Data
5.	Does the modified trait confer a selective advantage on the GMO under certain conditions?	Supporting Data
6.	If so, what are these conditions? Provide data on growth rates with and without selection pressure.	Supporting Data
7.	Would you expect the GMO to show any competitive advantages over its unmodified parent in mixed populations under the conditions in the test site? If so, what are the advantages?	Supporting Data

Experimental procedures, monitoring and contingency planning

1.	Describe in detail the overall experimental protocol for the release, including the protocol for control, test, and challenge organisms, if appropriate.	Supporting Data
2.	How many organisms are to be released?	Supporting Data
3.	How many releases of the GMO are proposed?	Supporting Data
4.	What are the arrangements for producing the GMO in quantity, transporting it to the site and accounting for the transported organisms?	Supporting Data
5.	How will the GMO be released?	Supporting Data
6.	What methods are to be used to test for batch to batch consistency if large scale production is required to produce GMOs for release?	Supporting Data
7.	What specific measures have been taken or will be taken in the production process to ensure the quality/purity of the GMO to be released?	Supporting Data

8.	How will the survival of the GMO be monitored? Provide a description of techniques for monitoring the presence of GMOs or transferred genetic material beyond the primary site, including specificity, sensitivity and reliability of detection methods.	Supporting Data
9.	If the release is likely to affect the characteristics or abundance of other species, how will this be monitored?	Supporting Data
10.	How will transfer of the introduced gene to other species be monitored?	Supporting Data
11.	What potential hazards or deleterious effects can be postulated and how are these to be evaluated during the release?	Supporting Data
12	Describe any structures or procedures that will be in place to reduce dissemination of the GMO.	Supporting Data
13.	If transfer of the inserted genetic trait to other organisms with adverse consequences is possible, what methods will be used to minimize these effects?	Supporting Data
14.	Will the GMO remain in the environment after the release? If so, (a) for what period of time, and (b) what might be the consequences?	Supporting Data
15.	Will measures be taken to reduce populations or dispose of the GMO once the release is completed? If so, provide details.	Supporting Data
16.	What monitoring is to be undertaken after the release is completed?	Supporting Data
17.	What contingency measures will be in place to remove the GMOs if a hazard becomes evident during the course of the release?	Supporting Data
18.	Describe site supervision procedures and any safety procedures undertaken by staff.	Supporting Data

Other assessments

1.	Have the same or similar GMO been used or released before, either within or outside CARICOM/CSME member countries? If so, what were the beneficial or adverse consequences? Provide references or reports of previous assessments.	General Information
2.	Has an overseas country refused an application for the use or release of this organism?	General Information
3.	What factors might suggest greater or less risk with the proposed use or release in CARICOM/CSME member countries?	General Information
4.	Has the GMO been imported? If so, provide documentation of quarantine clearance or assessment.	General Information
5.	Is there any reason to think that the GMO, if used or released in CARICOM/CSME member countries, could constitute a hazard, not discussed elsewhere in the proposal? If so, please explain.	General Information
6.	Provide any other information you may have that could assist with the assessment of this proposal.	General Information

B. PLANTS

If the plant is intended for human or animal consumption, answer also the questions in Section K.

1.	Has the parent plant an extended history of cultivation and of safe use? If not, explain.	A1
2.	What, if any, unintended pleiotropic effects, including undesirable effects on agronomic characteristics of the plant, may result from the expression of the transgene in the GMO (e.g. reduced fertility, increased disease prevalence, production losses, grain shedding)? Indicate the likelihood of these events.	C8, [C10]
3.	Describe the mechanism of pollen spread (by insect vectors or by other means) in the plant.	D3
4.	Provide any available data on pollen viability for the plant.	[C9], D2
5.	Indicate any potential pollinators and their range and distribution in CARICOM/CSME member countries.	D3
6.	Are any members of the genus of unmodified parent plants known to be weeds in any environment? If so, specify.	A3
7.	Are there any literature reports on cross-pollination between the species to which the GMO belongs and wild relatives known to be weeds? If so, please list.	D2, A6
8.	Provide quantitative data on successful cross-pollination between the plant and its wild relatives.	D2, A6
9.	If you know that sexually compatible plants live near the site of the release, give details and quantify the chances for cross-pollination.	D2
10.	If cross-pollination occurred, would the resulting plants survive/compete well? If not, why not?	D1
11.	Will the plants in this release be allowed to set seed? If not, is this planned for later releases?	D2
12.	If plants are allowed to set seed, does the mature seed normally remain contained within an ear, capsule, pod, etc. so that practically all of the seed can readily be harvested, or is the seed shed soon after it matures?	D2
13.	Can the seed be dispersed by natural mechanisms? If so, describe.	D3
14.	Are the seeds capable of being dormant for a long time? If so, how long?	[C9], D2
15.	Can the plant be dispersed by vegetative propagation? If so, describe the possible mechanisms.	D3
16.	What is the likelihood that the imparted characteristic could be integrated into other species, with adverse consequences?	D2
17.	If there is any possibility of such integration, would it have the potential to affect the distribution and abundance of the other species? If so, specify. Data on the factors which normally control populations of these other species in the natural environment (e.g. pathogens, herbivory, physiological stress) may be relevant.	[C6, D1, D8], D4
18.	If there is any possibility of such integration, has any attempt been made to minimize the risk (e.g. by imparting male sterility or other means of reproductive isolation)? If not, why not?	[C5], D7

19	How might the plant's competitive advantages (fitness) be changed: (i) in the agricultural setting; (ii) in the natural environment? Explain	D1
20.	Does the novel characteristic change the capacity of the plant to add substances to or subtract substances from the soil (e.g. nitrogen, toxic compounds)? If so, describe the change.	[C4], D4
21.	Is there any likelihood that the introduced gene could cause an increase in toxicity of the plant for animals and humans? If so, provide available data.	C2, E2
22.	Could any products of the plant concentrate in the natural or human food chain to level which become toxic? If so, explain.	C2, E3
23.	Is the biodegradability of the plant changed? If so, how?	D4
24.	What secondary ecological effects might result from release of the GMO (e.g. effect on endangered native species, resistance of insect populations to an insecticide, reduction or increases in numbers of prey or parasites)?	D4, [D8]
25.	If the construct involves resistance to a chemical agent (other than selective agents, such as antibiotics, used in strain construction): i. provide data on the degradability, selectivity and toxicity of the chemical concerned; ii. what is the agronomic significance of the chemical? iii. what is the biological activity of the chemical? iv. how is the chemical applied and used?	General Information, C6
26.	If the construct involves resistance to a herbicide, explain: i. what impact the release will have on use of that herbicide (provide forecasts on areas to be sprayed and volumes to be applied)? ii. what impact the release will have on total use of other herbicides and insecticides? iii. what impact the release will have on weed control? iv. what effect the release will have on the overall farming system? v. how the release will affect programmes designed to involve environmentally friendly chemicals or practices? vi. the role that the release will have in future pest management strategies.	General Information, C6

C. MICROORGANISMS LIVING IN OR ON ANIMALS

Questions here relate to organisms such as gut biota living in larger hosts, and micro-organisms applied externally to animals (e.g. bacteria to prevent fleece rot). Issues included here should also take into account the ecological interactions and behaviour of host organisms which could have environmental impacts.

1.	What is the animal host species?	C3
2.	Has the parent organism an extended history of use in agriculture? If so, please elaborate.	A1, C7

3.	Is there any evidence that the GMO might be capable of establishing in or on other animals, including feral animals? If so, what are these animals and what are the effects?	C3, D2
4.	What new capacity will the GMO provide for the host species? (e.g. ability to degrade plant or pasture toxins)?	C10
5.	What secondary effects can be postulated from conferring that capacity on the host?	C10
6.	Will the competitive advantage or ecological fitness of the host be altered? Explain, providing data to support your answer.	C10, D4
7.	What effects (including secondary effects) are likely on other plants or animals in the agricultural and natural environments? (Please include in your answer any likely effect on non-host animals or feral populations.)	D4, [D8]
8.	What secondary effects can be postulated from the introduction of the GMO into or onto the host? (For example, is there a possibility of the genetic insert being transferred to other organisms in the host, or to host cells?)	C10, D2
9.	For GMOs living in animals, will the GMO be excreted or otherwise leave the animal? If so, for how long does it survive outside the animal?	C5, [C9]
10.	What is the survival and dispersal of the GMO in natural waters and soil?	C1, C9 D2
11.	What could be the effects of the GMO on water quality?	D4
12.	Does the GMO produce spores?	C9
13.	Is the GMO resistant to desiccation?	C9
14.	What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
15.	Is the GMO susceptible to UV and ionizing radiation?	C6, D7

D. MICROORGANISMS AS LIVE VACCINES

1.	What disease is to be controlled by the use of this vaccine?	General Information
2.	On what host species is the vaccine to be used?	General Information, [C3]
3.	What is the host range of the parent organism from which the vaccine was constructed?	A7
4.	If the vaccine is intended for animals, what are the proposed target species/breeds for the vaccine? Specify age range, risk factor groups, and geographic area, if applicable.	General Information, [C3]
5.	Provide data regarding level and duration of immunity produced in the host species after vaccination with the GMO.	General Information, [C10]
6.	Over what period can the vaccine organism be detected in the vaccinated animals or their excretions? Provide supporting data.	General Information, [C9]

7.	Can the vaccine organism spread from vaccinated to non-vaccinated animals or to other species (including humans)? If so, what is the mechanism and frequency? Provide data, if available.	C3, D2
8.	Is there any evidence to indicate whether the susceptibility of the host to the vaccine organism could be affected by the current state of the host (e.g. immunosuppression or superimposition of other disease) or by other treatments (e.g. drugs)? If so, elaborate.	C10
9.	Does the genetic material of the vaccine organism have the potential to become incorporated in whole or in part into the genome of any cells of the vaccinated host?	D2
10.	If this is a viral vaccine, can the nucleic acid of the virus in the vaccine be rescued, or be restored to wild type, by recombination or complementation with intracellular viruses?	[B3], B5, D2
11.	In trials, is it proposed to dispose of waste which contains vaccine organisms? If so, describe the arrangements.	D7
12.	What is the fate of the vaccinated animals at the conclusion of the trial (in the case of an experiment)?	D7
13.	Will the vaccinated animals carry live vaccine organisms at the end of the trial? If so: i. will they be likely to disseminate the live vaccine organisms to their family contacts or to the general population? ii. what measures, if any, will be taken to minimize this possibility? iii. will the organisms be able to cross the placenta?	D2 D7 D2
14.	Is the use of this vaccine organism likely to preclude its use for vaccination against other diseases subsequently? Will its usefulness for other vaccinations be affected?	[C8]
15.	Is the vaccine likely to have any deleterious effects on pregnant humans or animals? If so, specify. For humans, provide data from animal models.	C2
16.	Is the vaccine teratogenic (i.e. causing developmental defects) for the foetus at any stage of gestation? If so, elaborate.	C2
17.	Does the GMO produce spores?	C9
18.	Is the GMO resistant to desiccation?	C9
19.	What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
20.	Is the GMO susceptible to UV and ionizing radiation?	C6, D7

E. MICROORGANISMS NOT FALLING INTO SECTIONS C OR D

Questions here relate to micro-organisms associated with plants and micro-organisms which might be applied to modify the physical or chemical environment (e.g. micro-organisms to modify soil properties).

1.	For micro-organisms associated with plants, what is the partner species of plant? Describe the specificity of the interaction and indicate the range of plant species with which the GMO can interact.	C3, [C10]
2.	Has the parent organism an extended history of use in agriculture? If so, please elaborate.	A1
3.	For micro-organisms associated with plants: i. what is the effect of the GMO on the partner plant species and how will this be monitored? ii. what other secondary effects might the GMO have on the plant? iii. does the modification cause any change to the range of host plant species available to the organism? iv. what effect of the GMO, if any, is anticipated on the distribution and abundance of the host plant species and other species with which the organism can interact?	C10 C3, [D8]
4.	If the GMO is associated with plant species which are food crops, could it affect the suitability of the resultant produce for human or animal consumption? If so, explain.	E1, E2, [E3, E4]
5.	What are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?	C4, D4
6.	What is the survival and dispersal of the GMO in natural waters and soil?	C1, C9, D2
7.	What could be the effects of the GMO on water quality?	D4
8.	Does the GMO produce spores?	C9
9.	Is the GMO resistant to desiccation?	C9
10.	What effects might the GMO have on soil organisms which are known to be beneficial to plants (e.g. *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and are likely to be in the test area?	D4, [D8]
11.	What is known about interactions between the GMO and closely related micro-organisms in the partner plant (if applicable) or the environment of the release site?	D2, D4
12.	For GMOs associated with plants, what effect might the GMO have on insects, birds and animals (including humans) which may eat the plant?	C2
13.	Does the GMO exchange genetic material with known plant pathogens? If so, elaborate.	D2
14.	What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
15.	Is the GMO susceptible to UV and ionizing radiation?	C6, D7

F. ANIMALS (VERTEBRATES, NOT INCLUDING FISH)

If the organism is to be consumed as a food, answer also the questions in Section K.

1.	What unintended effects (environmental, animal welfare or economic) may result from the release, and what is their likelihood?	C8

2.	Are any of the intended gains directly linked to changes in other characteristics of the species? If so, specify.	[C10]
3.	What effects might the expression of the modified trait have on the physiology, behaviour and reproduction of the animal? Explain, with data (e.g. studies from model animals).	C1, [C10]
4.	Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments or in the commercial phase?	D2
5.	Are the arrangements for handling any offspring the same as those for the experimental animals? If not, please specify the arrangements.	D7
6.	Do feral populations of the species exist in CARICOM/CSME member countries? If so: i. do the feral populations cause agricultural, environmental or disease-control problems? Specify the problems. ii. has any experimental work been done on the expression of the novel genetic material in feral animals (e.g. cross-breeding of GMOs with captive feral animals)? If so, what were the results? iii. what is the likelihood of the novel genetic material entering the feral gene pool (e.g. by interbreeding with modified farm animals)? iv. what effect might the entry of the novel genetic material into a feral gene pool have on the distribution and abundance of the feral population or on its ability to cause agricultural or environmental problems, or to contribute to the spread of infectious disease? Provide data to support your answer.	A3 A6, D2 D4
7.	If no feral populations exist in CARICOM/CSME member countries, comment on the likelihood that the imparted characteristic may enhance the ability of the species to establish feral populations.	C1, D1
8.	Can the GMO interbreed with any species native to CARICOM/CSME member countries?	D2
9.	What management procedures and environmental factors, if any, are required for optimal expression of the introduced trait? Provide data to support your answer.	D7

G. FISH AND AQUATIC ORGANISMS SUCH AS CRUSTACEANS

If the organism is to be consumed as a food, answer also the questions in Section K.

1.	Could the GMO produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	C2 C6
2.	What other unintended effects may result from the release? Please include consideration of the effect of the GMO on the community ecology at the release site.	[C3,D4] , C8
3.	Are any of the likely gains directly linked to losses in other characteristics of the organisms?	General Information
4.	Will the GMOs in this release be allowed to breed? If not, is breeding planned for later releases or commercial use?	D2
5.	Are the arrangements for handling any offspring the same as those for the experimental organisms? If not, please specify the arrangements.	D7

6.	Can the changed or added genetic material be transmitted by means other than by reproduction normal for the species or to any other species? If so, specify, and elaborate its effects.	D2, D3
7.	Do natural populations of the parental organism exist in CARICOM/CSME member countries (including in rivers, lakes, dams or coastal waters)? If so, do the natural populations cause problems with other organisms? Specify the organisms and the problems.	A3, A5
8.	If no natural populations of the organism to be modified exist in CARICOM/CSME member countries, could the modified characteristics enhance the ability of the species to establish populations in aquatic habitats?	C1, D1
9.	Has any experimental work been done on phenotypic expression of the novel genetic material in naturally occurring organisms (e.g. cross-breeding of GMOs with wild/farmed stocks)? If so, what were the results?	A6, D2
10.	What is the likelihood of the novel genetic material entering the gene pool of natural populations?	[A6], D2
11.	Could the entry of the novel genetic material into the gene pool of a natural organism have any effect on the distribution and abundance of the organism or on associated fisheries, the environment or public health? If so, please explain.	[C8, D8], D4
12.	What mechanisms will be used to prevent dispersal of the GMO into other ecosystems?	D7

H. INVERTEBRATES

If the organism is to be consumed as a food, answer also the questions in Section K.

1.	What effects might the GMO have on the food chain?	D4, [E3]
2.	Could the GMO produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	C2, C6
3.	What other unintended effects may result from the release? Your answer should include consideration of the effect of the GMO on the community ecology at the release site.	C8
4.	Will the GMOs in this release be fertile? If not, is it intended to use fertile organisms in later releases?	D2
5.	Are the genotype and phenotype of the offspring the same as those of the GMOs to be released? If not, please specify the differences.	General Information
6.	Do populations of the parental organism exist in CARICOM/CSME member countries? If so, do these populations cause agricultural, environmental or public health problems or benefits? Specify the problems or benefits.	A3, A5
7.	Can the changed or added genetic material be transmitted by means other than reproduction normal for the species? If so, specify, and elaborate its effects.	D2, D3
8.	What is the likelihood of the novel genetic material entering gene pools of natural populations?	[A6], D2
9.	Can the changed or added genetic material be transmitted to any other species? If so, specify the mechanism of transfer and list the species.	D2

10.	Has any experimental work been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (e.g. cross-breeding of modified strains with wild/caught stock)? If so, what were the results?	A6, D2
11.	Could the entry of the novel genetic material into the gene pool of natural populations of the organism have any effect on the distribution and abundance of the natural populations? What would be the effect of this change?	D4, [C8, D8]
12.	What mechanisms will be used to prevent dispersal of the GMO into other ecosystems?	D7

I. ORGANISMS FOR BIOLOGICAL CONTROL

1.	What is the species targeted for biological control?	[C3]
2.	What direct effects does the parent organism have on the target species?	General Information
3.	What direct effects does the GMO have on the target species?	C10
4.	What is the host range of the GMO? If the host range of the GMO is likely to be different from that of the parent organism, explain why.	C3
5.	What non-target organisms have been tested for susceptibility to the GMO?	D8
6.	What is the rationale for the choice of species tested?	General Information
7.	How is the GMO transferred from one target individual to another and what factors affect this transferability?	D2, D3
8.	What secondary effects can be envisaged on predators, prey or parasites of the target species?	D4, D8
9.	Explain the consequence of the removal or reduction of the target species on the management of agriculturally significant plants or farm animals.	D4
10.	Predict any change in the ecosystem resulting from a reduction in the population of the target organism.	D4
11.	Does the GMO produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, elaborate.	C2, E3
12.	If the modified genetic traits can be transmitted to other organisms which are likely to be in the environment, are these other organisms likely to affect non-target species?	D2, [D3], D8
13.	What genetic response might be invoked in populations of the target organism as a result of the use of the GMO (e.g. increased resistance to the modified organism)? What evidence is there for this response?	[C3,C10], C8

J. ORGANISMS FOR BIOREMEDIATION

1.	What is the target substrate for bioremediation?	General Information

2.	What effect does the parent organism have on the target substrate?	General Information
3.	What effect does the GMO have on the target substrate?	[GI]
4.	What other substances can be metabolized by the GMO which cannot be metabolized by the parent organism?	C4
5.	Will the GMO be self-sufficient once exposed to the target substrate or will additional measures be required (e.g. provision of supplementary nutrients and growth factors or other environmental modifications)?	C5
6.	Does the GMO produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, specify.	C2, E3, [C8]
7.	What effects might the GMO have on water, air or soil quality?	D4
8.	What effects might the GMO have on organisms which ingest it?	D8, E2
9.	Will the GMO be dispersed from the site of application? If so, describe the mechanisms involved and the consequences.	D2, D3

K. ORGANISMS TO BE CONSUMED AS FOOD

1.	Is the parent organism or the donor organism already used in food production or eaten as food? If so, (i) at what level of daily/weekly intake, and (ii) is any processing needed or commonly used before consumption?	E1
2.	Does the GMO produce metabolites which may have adverse effects on the consumer (humans or animals)? If so, elaborate. Provide available data on toxicology, allergenicity and other possible adverse effects.	E2, E3
3.	Can any products of the GMO concentrate in the food chain to levels which may become toxic? If so, elaborate.	E3
4.	Will the nutritional quality of the food be changed by the genetic modification? If so, how?	E1
5.	Is the GMO to be processed during the production of the food? If so, elaborate.	General Information
6.	Is the GMO the major component of the food as eaten, or is it in small numbers in the final product?	E4

ANNEX 4a. GUIDANCE FOR MINIMUM FARM ISOLATION DISTANCES

(To be considered for tripling in the case of Guyana for direct release of LMOs/GMOs into the environment when all other risks are considered minimal but need several kilometres isolation from organic agriculture farms.)

Isolation distances as required by USDA for producing foundation seed used for seed increase. Note that this is not a complete list of all crops.

CROP SPECIES [a]	**DISTANCE, ft**	**MAXIMAL PROPORTION CONTAMINATED, %** [b]
No isolation required:		
Barley	0	0.05
Bean, field and garden	0	0.05
Broad bean	0	0.05
Cotton	0	0.03
Flax	0	0.05
Millet, selfed	0	0.05
Mung bean	0	0.10
Oat	0	0.02
Pea, field	0	0.50
Peanut	0	0.10
Soybean	0	0.10
Triticale	0	0.05
Wheat	0	0.50
Isolation Required:		
Alfalfa	600	0.10
Buckwheat	660	0.05
Clover, < 2 ha	600	0.10
Clover, > 2 ha	900	0.10

Corn	660	0.10
Crown vetch, < 2 ha	200	0.10
Crown vetch, > 2 ha	900	0.10
Grasses, cross-pollinated	900	0.10
Grasses, selfed	60	0.10
Lespedeza	10	0.10
Millet, cross-pollinated	1,320	0.005
Mustard	1,320	0.05
Okra	1,320	0.0
Onion	5,280	0.0
Pepper	200	0.0
Rape, cross-pollinated	1,320	0.05
Rape, selfed	660	0.05
Rice	10	0.05
Rye	660	0.05
Safflower	1,320	0.01
Sorghum	900	0.005
Sunflower	2,640	0.02
Tobacco	150	0.01
Tomato	200	0.0
Trefoil, birdsfoot	600	0.10
Vetch	10	0.10
Vetch, milk	600	0.05
Watermelon	2,640	0.0

[a] Common name.
[b] Maximal percentage produced from pollen outside plot.
(Source: From Regulations listed in Table 5 of USDA (1994a).)

ANNEX 4b. GUIDANCE LIST OF SOME RELEVANT CROP SPECIES

(For consideration in the case of Guyana for direct release of LMOs/GMOs into the environment when all other risks are considered minimal but need several kilometres isolation from organic agriculture farms.)

Examples of Commercially Important Species that can hybridize with Wild Relatives in the Continental United States [List revised and adapted for Guyana].

Family and Cultivated Species [a]	**Wild Relative [a]**
Apiaceae	
Apium graveolens (celery)	Same species
Daucus carota (carrot)	**Same species (wild carrot)**
Chenopodiaceae	
Beta vulgaris (beet)	*B. vulgaris var. maritima* (hybrid is a weed)
Chenopodium quinoa (quinua, a grain)	*C. berlandieri*
Compositae	
Chicorium intybus (chicory)	**Same species**
Helianthus annuus (sunflower)	**Same species**
Lactuca sativa (lettuce)	*L. serriola* (wild lettuce)
Cruciferae	
Brassica napus (oilseed rape;canola) [b]	**Same species, *B. campestris, B. juncea***
Brassica rapa (turnip)	**Same species (= *B. campestris)***
Raphanus sativus (radish)	**Same species, *R. raphanistrum***
Cucurbitaceae	
Cucurbita pepo (squash)	**Same species** (= *C. texana,* Wild squash)
Ericaceae	

Vaccinium macrocarpon (cranberry)	Same species
Vaccinium angustifolium (blueberry)	Same species
Fabaceae	
Trifolium spp. (clover)	**Same species**
Medicago sativa (alfalfa)	Same species
Liliaceae	
Asparagus officinalis (asparagus)	Same species
Poaceae	
Avena sativa (oat)	***A. fatua*** (wild oats)
Cynodon dactylon (bermuda grass)	**Same species**
Oryza sativa (rice)	**Same species** & others (red rice)
Saccharum officinarum (sugar cane)[c]	***S. spontaneum*** (wild sugarcane)
Sorghum bicolor (sorghum)	***S. halepense*** (johnsongrass)
	Same Species[d] (shattercane)
Triticum aestivum (wheat)	***Aegilops cylindrica*** (jointed goatgrass)[e]
Solanaceae *Nicotiana tabacum* (tobacco)	Same species
Vitaceae	
Vitis vinifera (grape)	***Vitis*** spp. (wild grape)

a. Wild relatives recognized as weeds (unwanted species in agricultural or other habitats) are underlined; those also included in the worst 100 weeds worldwide (Holm *et al*., 1997) or Federal Noxious Weed List are in boldface. This list is not exhaustive, especially for landscaping and forage species. For some cultivars, the extent of hybridization has not been studied.
b. Also hybridizes with *Raphanus raphanistrum*, but evidence to date suggests that crop chromosomes do not recombine with wild genome and are lost after several generations (Chevre *et al*., 1997; Chevre *et al.*, 1999).
c. Cultivated sugar cane does not need to flower before harvest, but hybrids can occur (Stevenson, 1965).
d. From Burnside (1968).
e. From Zemetra *et al.* (1998).

(Source: Adapted from Snow and Morán-Palma (1997).)

ANNEX 5. BASIC ELEMENTS OF THE DRAFT BIOSAFETY BILL FOR GUYANA

II. Part 1 – **General Provisions**

a. Article 1 – **Objectives**

i. Guide the judicious use of modern biotechnology in Guyana for sustainable development in ways, which do not harm or jeopardise human or environmental health including Guyana's biodiversity and genetic resources in accordance with the precautionary principle, with limited permissive approach where the use of the products of modern biotechnology have been scientifically proven to be biological safe on the basis of current information;

ii. Ensure effective control of trans-boundary movement of GMOs or products resulting from modern biotechnology through exchange of information and a scientifically based, transparent and predictable system for review and decision-making and of advance informed agreement; and

iii. To implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol) in Guyana.

b. Article 2 – **Definitions** [note: the following terms are defined in harmony with international definitions]

i. Accident
ii. Applicant
iii. Biodiversity
iv. Biosafety Clearing-house
v. Cartagena Protocol
vi. Code
vii. Competent Authority
viii. Contained use
ix. Controlled area
x. Deliberate release
xi. Designated Competent Authority
xii. Ecosystem
xiii. Ecosystem health
xiv. Environment
xv. Export
xvi. Exporter
xvii. Facility
xviii. Food
xix. Genetically engineered
xx. Genetically modified
xxi. Genetically modified food
xxii. Genetically modified organism
xxiii. Healthcare product
xxiv. Import

xxv. Importer
xxvi. Institutional biosafety committee
xxvii. Inspectorate
xxviii. Intentional introduction into the environment
xxix. Interested party
xxx. Living modified organism
xxxi. Living organism
xxxii. Modern biotechnology
xxxiii. Minister
xxxiv. National Competent Authority
xxxv. National Focal Point
xxxvi. Operator
xxxvii. Person
xxxviii. Placing on the market
xxxix. Registry
xl. Risks to environment
xli. Risks to human health
xlii. Secretariat.

c. Article 3 – Scope – Application of the Act

This Act shall apply to the following GMOs:

1. Genetically modified organisms intended for contained use according to biosafety containment levels 1, 2, 3, and 4.
2. Genetically modified organisms for intentional release into the environment within the legal boundaries of Guyana.
3. Genetically modified organisms intended for import or export that may have an adverse effect on the conservation and sustainable use of Guyana's biological diversity, taking also into account any potential risks to human and ecosystem health.

d. Article 4 – Purpose of the Act

In accordance with Article 1, the purpose of this Act is to provide the legal infrastructure and mandate for the regulation of biosafety and biotechnology and any related biosecurity matters in accordance with Guyana's obligations under the Cartagena Protocol on Biosafety.

e. Article 5 – Precautionary Principle

This Act requires the need for caution in the decision-making process on all genetically modified organisms intended for use in or transport through Guyana even where there is lack of adequate scientific evidence on the potential risks posed by such organisms to the biological diversity, food safety, human health and the environment within the legal boundaries of Guyana.

f. Article 6 – Act binds the State

This Act binds the Cooperative Republic of Guyana.

III. Part 2 - **Institutional and Administrative Arrangements**

a. Article 7 – Establishment of the National Biosafety Authority

For the purposes of this Act, there is hereby established a National Biosafety Authority which shall consist of no less than fifteen and no more than twenty-one members appointed by the Minister representing the following:

i. Two Representatives of the Environmental Protection Agency drawn from:
    1. The Environmental Management Division of the EPA;
    2. The Natural Resource Management Division of the EPA;
ii. Director of Food and Drugs Department of the Ministry of Health or legal designate;
iii. Director of National Agricultural Research Institute or legal designate;
iv. Director of Institute of Applied Science and Technology or legal designate;
v. Commissioner of Forests or legal designate;
vi. Chairman of the Pesticides and Toxic Chemicals Control Board or legal designate;
vii. Chairman of the National Commission of Codex Alimentarius or legal designate;
viii. Representative of the Private Sector Commission;
ix. Representative of the Amerindian Community;
x. Representative of the Farmers' Association;
xi. Representative of the Guyana Consumers Association;
xii. Representative of the National Science Research Council;
xiii. Representative of the University of Guyana;
xiv. Representative of the Guyana Biotechnology Corporation;
xv. Representative of the Religious community;
xvi. Representative of the Minister of Health other than the Director of Food and Drugs;
xvii. Representative of the Minister of Industry, Commerce and Tourism;
xviii. Representative of the Minister of Foreign Trade and International Cooperation;
xix. Representative of the Attorney-General and Minister of Legal Affairs;
xx. Representative of the Guyana Forestry Commission;
xxi. Representative of the Lands and Surveys Commission;
xxii. Representative of the Organic Farmers' Association; and
xxiii. Representative of any other most relevant agency.

The Minister shall ensure at least two thirds of the appointees have a very basic or reasonable knowledge of the elementary issues relating to biotechnology and biosafety.

b. Article 8 – NBA as National Competent Authority
    i. Name of agency

The National Competent Authority on all biosafety matters shall be the NBA.

ii. Primary functions of NBA (or NBA)
The National Biosafety Authority (NBA) [or National Biosafety Authority (NBA)] shall:

1. Advise the Minister, other ministries and appropriate agencies and bodies on all biosafety matters pertaining to the application, development, production, release, transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral vectors;
2. Ensure all biosafety activities relating to the development, release, transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral vectors, are performed in accordance with the provisions of this Act;
3. Ensure compliance with all the regulations on biosafety under this Act; and
4. Perform such other duties and responsibilities as required by the Minister on the implementation of the Cartagena Protocol.

iii. NBA as National Focal Point on Biosafety
In accordance with this Act, the NBA is hereby designated the National Focal Point of the Cartagena Protocol.

iv. Primary functions of NBA as National Focal Point
The NBA hereby designated as the National Focal Point of the Cartagena Protocol shall:

1. Perform all the administrative functions required under the State's obligations as enshrined in Article 19 of the Cartagena Protocol;
2. Ensure all administrative and functional requirements of the Cartagena Protocol are met; and
3. Perform such other duties and responsibilities as required by the Minister on the implementation of the Cartagena Protocol.

c. Article 9 – Duties of the NBA

In accordance to the functions provided in Article 8, the NBA shall:

i. Establish an application procedure on all biosafety activities relating to the development, release, transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral vectors;
ii. Implement all procedures for GMO biosafety applications through its Secretariat;
iii. Receive and process biosafety applications through its relevant bodies;
iv. Implement all procedures for GMO risk assessment through its Secretariat;
v. Receive and process GMO risk assessment reports through its relevant bodies;
vi. Ensure conformity of all applications as required by this Act;
vii. Prescribe designated areas for trial releases of GMOs after satisfactory risk assessment;

viii. Act as a repository of all relevant national and regional biosafety documentation;
ix. Require the Secretariat to maintain a register of:

1. All applications made pursuant to the requirements of this Act;
2. The particulars of all GMOs that have been approved in accordance with this Act;
3. The particulars of all GMO contained use facilities;
4. The particulars of all GMO trial releases in designated areas;
5. Names and addresses of persons, companies or any entity engaged in approved activities relating to the development, release, transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral vectors, either for research, commercial purposes or human health, plant health or veterinary use;
6. National and regional roster of biosafety experts – when necessary the relevant international roster shall be maintained;
7. All national GMO notifications;
8. All national and sub-regional accidental GMO release notifications;
9. All national and sub-regional accidental GMO release investigation reports;
10. All notifications of national and sub-regional transboundary movement of GMOs within the obligations of the Caribbean Single Market; and
11. Establish a register of all institutional biosafety committees and their composition for relevant organizations and institutions.

d. Article 10 – Appointment of the Chair of the NBA

The Minister shall designate a Chairperson from among the nominees of the NBA. Such person, though not required to be endowed with technical competence in biotechnology and biosafety issues, shall be required to have reasonable functional understanding of biotechnology and biosafety issues in order to ensure effective deliberations of the Authority.

e. Article 11 – Appointment of the Deputy Chair of the NBA

The Minister shall designate a Deputy Chairperson from among the nominees of the NBA. Such person, though not required to be endowed with sound technical competence in biotechnology and biosafety issues, shall be required to have reasonable functional understanding of biotechnology and biosafety issues in order to ensure effective deliberations of the Authority.

f. Article 12 – Vacancies in the NBA

A vacancy shall be deemed to have occurred on the following grounds:

i. A member ceases to be an officer within the agencies and bodies listed in Article 7;
ii. A member is absent without leave or notification of the Authority or Chairman for more than three consecutive meetings;
iii. A member resigns;

iv. A member becomes intellectually invalid to exercise basic analytical and reasoning skills; or
v. A member dies.

g. Article 13 – Meetings of the NBA

i. The NBA shall meet at such times and as often as may be required to perform its functions and duties as required under this Act, but shall meet at least four times in a calendar year;
ii. The NBA may convene special working groups as deemed necessary for the efficient discharge of its responsibility, but the final authority to take and implement decisions shall be vested in the full membership or stipulated quorum thereto;
iii. The quorum of any meeting shall be one more than fifty percent of the constituted total membership including the Chairperson or deputy Chairperson;
iv. The NBA may determine and agree among its membership its own procedures for the conduct of meetings and the format of minutes of meetings;
v. The NBA may co-opt any competent or knowledgeable persons to serve temporarily in order to provide technical or other advice when deemed necessary;
vi. The NBA may invite written comments and technical briefs from any competent or knowledgeable persons when deemed necessary;
vii. All approved matters and recommendations by the Council or Authority shall be transmitted by the Chairperson to the Minister; and
viii. The Biosafety Commissioner shall act as Secretary to the Council or Authority.

h. Article 14 – The Secretariat

i. During the first two (2) years of its establishment, the Secretariat shall be housed by a semi-autonomous Biosafety Division within the Environmental Protection Agency through a three- to four-year implementation phase of this framework as per the global and or regional biosafety frameworks implementation project.
ii. The NBA Secretariat may exercise such powers and perform such duties as may be conferred upon or delegated or assigned by the Authority under this Act.

i. Article 15 – Functions of the Secretariat

Subject to the instructions of and conditions prescribed by the Board of the Authority, the Secretariat shall:

i. Receive and ensure the processing of all applications through the appropriate mechanisms established by this Act;
ii. Issue biosafety Certificate of Approval or Authorization with authorized seal of the Authority as prescribed by the Act;
iii. Coordinate biosafety research and development;
iv. Ensure public education and awareness on relevant issues pertaining to biotechnology, biosafety and biosecurity in a timely manner;
v. Promote accumulation of knowledge, dissemination of information, create active dialogue between researchers and other specialists, politicians and other citizens;

vi. Draw up, implement and monitor appropriate occupational safety protocols with respect to GMOs at work places where biotechnology procedures are used or products handled;
vii. Advise on appropriate labelling of GMOs in feedstuffs and feeds sold in or imported to or through Guyana;
viii. Defend the image of the country in the field of biotechnology, biosafety and biosecurity;
ix. Create and maintain a bio-informatics database as well as a biosafety information and promotion website;
x. Establish criteria for in-house Institutional Biosafety committees where relevant;
xi. Serve notice to require importers and exporters of material believed to be GMO to file an application;
xii. Furnish a Biosafety Inspector with appointment letter or certificate and an identification badge of authority;
xiii. Furnish a Biosafety Inspector with all the guidelines and regulations of the Council or Authority;
xiv. Ensure all Biosafety Inspectors have the requisite training for the effective and efficient discharge of their duties under this Act;
xv. Issue cessation orders on the recommendation of the Council/Authority;
xvi. Ensure compliance of all biosafety regulations;
xvii. On the recommendation of the Board, shall have cause to amend or withdraw a Certificate of Approval or Authorization issued under this Act.

j. Article 16 – The Biosafety Commissioner

There shall be a Biosafety Commissioner appointed as administrative head of the Authority.

k. Article 17 – Appointment of the Biosafety Commissioner

i. A Biosafety Commissioner shall be appointed through a competitive selection process based on an open vacancy announcement in the local media;
ii. The Council shall constitute such committee as a search committee or appointment committee to screen applicants and make a selection;
iii. Such person so selected shall be required to have technical knowledge in biological, environmental or medical sciences, environmental law or any other related and relevant discipline but with a sound knowledge of and background or working experience in biosafety and biotechnology related issues.

l. Article 18 – Establishment of the Biosafety Inspectorate Unit

In accordance with this Act, a National Biosafety Inspectorate is hereby established.

m. Article 19 – Functions of the Biosafety Inspectorate Unit.

In accordance with this Act and the biosafety requirements, the functions of the Biosafety Inspectorate, in collaboration with inter-agency institutions, shall be, but not restricted to, the

following:

i. Agricultural law enforcement, crops and livestock disease control, registration of livestock importation and agricultural products;
ii. Environmental impact assessment and food safety review functions;
iii. Industrial practices review and import/export management functions;
iv. Occupational safety and health standards related to biosafety;
v. Food safety standards related to biosafety;
vi. Drug safety standards related to biosafety;
vii. Medical biotechnology interventions related to biosafety;
viii. Customs and excise functions with respect to GMOs;
ix. Border control and forensic science with respect to GMOs;
x. Inspection and enforcement of institutional coordination functions related to biosafety; and
xi. Marine research management, stock assessment and impact assessment processes.

n. Article 20 – Biosafety Inspectors

Biosafety inspectors shall be the monitoring and enforcement officers under this Act. They may include officers of other regulatory and law enforcement agencies so designated by the NBA.

o. Article 21 – Appointment of Biosafety Inspectors

Biosafety Inspectors shall be appointed by the Head of the Secretariat on the recommendations of the Board of the NBA and shall receive an instrument of appointment together with a prescribed identification badge.

p. Article 22 – Powers of Biosafety Inspectors

Biosafety Inspectors under the authority of the NBA shall have the power to:

i. Confiscate any suspected illegal GMO or products thereof;
ii. Serve cessation orders on biotechnology activities deemed risky or unapproved; and
iii. Request for inspection from anyone using GMOs, the certificate of authorization.

q. Article 23 – Establishment of National Biosafety Clearing-house

i. Name of National Biosafety Clearing-house Committee
Upon the enactment of this Act, the National Biosafety Clearing-house Task force shall become established as the National Biosafety Clearing-house Committee.

ii. Primary functions of the National Biosafety Clearing-house Committee
The primary functions of the National Biosafety Clearing-house Committee shall be as prescribed under the guidelines for the National BCH Task Force.

iii. National Biosafety Clearing-house Committee as BCH Focal Point within NBA

Secretariat

In accordance with this Act and in meeting Guyana's obligations under the Cartagena Protocol, the National Biosafety Clearing-house Committee shall be designated the BCH Focal Point within NBA Secretariat.

r. Article 24 – Establishment of Biosafety Scientific Advisory Committee

i. Name of the Advisory Committee

The Biosafety Scientific Advisory Committee of the NBA is hereby established.

ii. Primary responsibilities of the Biosafety Scientific Advisory Committee

The Biosafety Scientific Advisory Committee established within the NBA shall be charged with the responsibility of reviewing all activities of a potential bio-hazardous nature. Its primary responsibilities are to:

1. Review all approved projects involving, the use of recombinant DNA molecules, carcinogens, infectious disease agents, and other potentially dangerous materials which are not exempt from such reviews;
2. Report approvals and non-compliance in accordance with established guidelines; and
3. Recommend training and approve personnel engaged in such activities.

iii. Composition of the Biosafety Scientific Advisory Committee

The Biosafety Scientific Advisory Committee shall consist of a minimum of five members and a maximum of 10 voting members. Collectively, the membership shall have experience and expertise in research with microbial pathogens, chemical toxicology, and recombinant DNA and be aware of any potential risks to public health and the environment.

iv. Appointment of members

Members of the Biosafety Scientific Advisory Committee shall be appointed by the Board of the NBA, with endorsement by the Minister. All appointments to the Committee shall be for a three-year term.

Membership should be from the following fields of scientific expertise:

1. Agronomy;
2. Animal Breeding and Genetics;
3. Animal Pathology;
4. Plant Breeding and Genetics;
5. Plant Pathology;
6. Environmental Toxicology;
7. Plant Ecology;
8. Animal Ecology;
9. Entomology;

10. Veterinary Microbiology;
11. Medical Microbiology;
12. Plant Biotechnology and Molecular Biology;
13. Animal Biotechnology and Molecular Biology;
14. Virology; and
15. Weed Science.

v. Establishment of appropriate Sub-committees of the Biosafety Scientific Advisory Committee

The Biosafety Scientific Advisory Committee can appoint Sub-Committees as appropriate.

s. Article 25 - Public disclosure of possible conflicts of interest

All members of the NBA, the Biosafety Scientific Advisory Committee, and officers of the Secretariat shall be required to deposit a certificate of conflict of interest disclosure with the Secretariat, which shall be made public by way of public notice in the local newspapers.

t. Article 26 - Code of Ethics

i. To ensure high moral standards in the discharge of its duties, the NBA shall establish an acceptable Code of Ethics within three months of the appointment of the Council or Authority;

ii. The prescribed code shall at the minimum include the following elements:

1. Fairness based solely on scientific and technical veracity of decisions;
2. Discharge of duties without fear or favour;
3. Prohibition from receipt of any gifts from applicants;
4. Prohibition from disclosure of confidential information;
5. Prohibition from offering personal technical advise to applicants;
6. Prohibition from personal actions deemed advantageous or disadvantageous to an applicant;
7. Upholding professionalism at all times; and
8. Any other appropriate tenet.

u. Article 27 - Internal Procedures of the Biosafety Scientific Advisory Committee and related subcommittees

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices, internal procedures for the work of the Biosafety Scientific Advisory Committee.

IV. Part 3 – **Notification and Authorization requirements**

a. Article 28 – Prohibitions relevant to specific categories of LMOs/GMOs

i. LMOs/GMOs shall be classified according to the expected risk level whether they are GMOs of recognizable size to the naked eye or genetically Modified Micro-organisms

(GMMs), and thereby considered microscopic;

ii. All GMOs not approved for use and release into the environment in the OECD countries shall be prohibited;

iii. All GMOs for which there exists any tangible global controversy on the basis of inadequate risk determination shall be prohibited;

iv. The categories of GMOs requiring notifications and authorizations include, but not limited to:

1. GMOs and related living products intended for food, feed and for processing;
2. GMOs for contained use;
3. GMOs for deliberate release into the environment;
4. GMOs for placement on the market; and
5. GMOs for medical and pharmaceutical use, notwithstanding the Article 5 of the Cartagena Protocol.

b. Article 29 – Public notice on intent to prohibit importation

When a determination has been made by the Authority on the intent to prohibit the importation of any GMO or related products, the secretariat shall cause to be published a notice in the local newspapers on such guidance as deemed relevant and necessary.

c. Article 30 – Control of GMOs/LMOs

The control of GMOs/LMOs shall be determined by guidelines set by the Authority with due regard to the classification under of biosafety levels 1, 2, 3, 4 on the basis of whether it is a small or large scale operation.

d. Article 31 – Notification Requirements and Procedures for contained use activities

For the purposes of this Act, contained use shall require the following:

i. Expert opinion from the Biosafety Advisory Scientific Committee;
ii. Fulfilment of all biosafety levels 1, 2, 3 and 4 requirements;
iii. Categorization of the biosafety level;
iv. Compliance with Occupational Safety and Health Act;
v. EIA;
vi. Risk assessment statement including details as per Schedule 3;
vii. Inspection of the premises on which contained use is to be fulfilled;
viii. Detailed characteristics of the GMO as per Schedule 3; and
ix. Specified containment measures.

e. Article 32 – Import/Export Restrictions for GMOs

Under the guidance of the NBA, the Secretariat shall prepare and cause to publish a list of import and export restrictions for GMOs within six months of the coming into force of this

Act.

f. Article 33 – Application Procedures for Import/Export Permit

In accordance with this Act, details of all application procedures shall be as approved by the NBA, and shall include all the details contained in the Schedule 1.

g. Article 34 – Confidential Information

The applicant shall be required to indicate which material in the application shall be deemed confidential. The relevant Committee of the NBA shall review the provision and advise the Secretariat appropriately following the guidelines of the Cartagena Protocol.

h. Article 35 – Acknowledgement and preliminary response to application

All applications shall be reviewed for completeness by the Secretariat and the applicant shall be provided with an acknowledgement letter within seven (7) days of receipt of the said application.

i. Article 36 – Authorization requirements for deliberate introduction into the environment

In accordance with this Act, Authorization requirements for deliberate introduction into the environment shall require the following:

i. Detailed characteristics of the GMO as per schedule in Biosafety Bill;
ii. Compliance with all environmental management guidelines under the EPA Act;
iii. Expert opinion from the Biosafety Advisory Scientific Committee;
iv. Compliance with Occupational Safety and Health Act;
v. EIA;
vi. Risk assessment statement including details as per schedule in Biosafety Bill; and
vii. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and keystone species.

j. Article 37 – Import Permit

Import permits shall require the filing of an application which shall include all the stipulations under the Schedule 1.

k. Article 38 – Export Permit

Export permits shall require the filing of an application which shall include all the stipulations under the Schedule 1.

l. Article 39 – Biotechnology Research & Development Permit as per sector

i. Agricultural Biotechnology Research & Development use of GMOs and related products shall require the following:

1. Detailed characteristics of the GMO as per schedule in Schedule 1;
2. Compliance with all environmental management guidelines under the EPA Act;
3. Expert opinion from the Biosafety Scientific Advisory Committee;
4. Compliance with Occupational Safety and Health Act;
5. Environmental Impact Assessment;
6. Risk assessment statement including details as per Schedule 2; and
7. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and keystone species.

ii. Environmental Biotechnology Research and Development use of GMOs and related products shall require the following:

1. Detailed characteristics of the GMO as per Schedule 1;
2. Compliance with all environmental management guidelines under the EPA Act;
3. Expert opinion from the Biosafety Scientific Advisory Committee;
4. Compliance with Occupational Safety and Health Act;
5. Environmental Impact Assessment;
6. Risk assessment statement including details as per Schedule 2; and
7. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and keystone species.

iii. Food Biotechnology Research and Development use of GMOs and related products shall require the following:

1. Detailed characteristics of the GMO as per Schedule 1;
2. Compliance with all environmental management guidelines under the EPA Act;
3. Expert opinion from the Biosafety Scientific Advisory Committee;
4. Compliance with Occupational Safety and Health Act;
5. Environmental Impact Assessment;
6. Risk assessment statement including details as per Schedule 2; and
7. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and

keystone species.

iv. Industrial Biotechnology Research and Development use of GMOs and related products shall require the following:

1. Detailed characteristics of the GMO as per Schedule 1;
2. Compliance with all environmental management guidelines under the EPA Act;
3. Expert opinion from the Biosafety Scientific Advisory Committee;
4. Compliance with Occupational Safety and Health Act;
5. Environmental Impact Assessment;
6. Risk assessment statement including details as per Schedule 2; and
7. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and keystone species.

v. Medical Biotechnology Research and Development use of GMOs and related products shall require the following:

1. Detailed characteristics of the GMO as per schedule in Schedule 1;
2. Compliance with all environmental management guidelines under the EPA Act;
3. Expert opinion from the Biosafety Scientific Advisory Committee;
4. Compliance with Occupational Safety and Health Act;
5. Environmental Impact Assessment;
6. Risk assessment statement including details as per Schedule 2; and
7. Biodiversity impact statement identifying the possibilities, if any, for gene introgression and horizontal gene transfer between the GMO and local biodiversity with particular emphasis on the national endemic species and keystone species.

m. Article 40 – Medical use Permit
Medical use permits shall require the filing of an application which shall include all the stipulations under the Schedule 1.

n. Article 41 – Issuance of Permit

Upon satisfactory review and recommendation of the Biosafety Scientific Advisory Committee to the NBA Board, the Secretariat shall issue a permit.

o. Article 42 – Simplified Application and review procedures for Pre-approved GMOs

i. Application procedure for Pre-approved GMOs

All applications for pre-approval shall include a checklist based on Schedule 1 indicating the status of prior knowledge and approval of GMOs of identical nature;

ii. Contents of Application for Pre-approved GMOs;

iii. Approval process

The approval process shall require:

1. Filing of application as per the requirements of this Act and the schedules thereto;
2. Review of the application by the Biosafety Scientific Advisory Committee, and submission of a report with recommendations to the NBA Board;
3. Review of the Biosafety Scientific Advisory Committee's report by the Board;
4. Decision by the Board;
5. Transmittal of the decision to the Secretariat;
6. Transmittal of the decision to the applicant.

iv. Public notification

The Secretariat shall cause to be published a public notification on the Board's decision.

v. Registration of public notice

All public notices on approvals and disapprovals shall be registered in prescribed form in at the Secretariat.

vi. Decision on application for Pre-approved GMOs

vii. Registration of Pre-approved GMOs

The Secretariat shall cause to be published the registered list of all Pre-approved GMOs and related products.

p. Article 43 – Petition for exemption or simplified procedures for Pre-approved GMOs

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

q. Article 44 – Prohibitions on handling, transportation, in-transit, use, transfer or release of GMO without permit

V. Part 4 – **Risk Assessment and Management Measures**

a. Article 45 – Risk assessment process

Risk assessment requirements shall be as stipulated in Schedule 2.

b. Article 46 – Evaluation of Risk Management system

The designated committee of the NBA, the Biosafety Scientific Advisory Committee, shall review the risk management process provided in accordance with the requirements of this Act and all related guidelines mandated by the NBA from time to time.

c. Article 47 – Review of risk assessment report

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

d. Article 48 – Responsibility for risk management measures

Full responsibility for the implementation of the risk management measures approved by the NBA as part of the application shall devolve solely on the Applicant. However, in accordance with this Act, the NBA reserves the right to conduct both prior consent and unannounced monitoring and surveillance inspections as the Authority deems fit.

e. Article 49 – Risk management measures

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

f. Article 50 – Labelling of GMOs and related products
[to be developed]

g. Article 51 – Packaging of GMOs
[to be developed]

h. Article 52 – Accompanying Documentation for transport of GMOs
[to be developed]

VI. Part 5 **– Decision-making and Communication of Decision**

a. Article 53 – Decision on Risk assessment report

i. Decisions on risk assessment reports shall be conveyed to the applicant in writing within the prescribed duration of ninety days;
ii. A copy of the decision shall be registered in the Authority's register of decisions;
iii. A summary of the decision shall be deposited in the database of the national Biosafety Clearing-house, with simultaneous transmission to the regional and Central Portal of the Biosafety Clearing-house; and
iv. The Secretariat shall cause to be published in the local newspapers a public notice of the decision.

b. Article 54 – Communication of decision to Applicant

The decision shall be transmitted in writing to the applicant by the Secretariat with the authorized signature and seal of the Authority.

VII. Part 5 – **Mechanism for Review of Decisions**

a. Article 55 – Review of decisions

Within reasonable expectation and in fairness to the applicant, a request for review of all decisions shall be entertained under the following conditions:

i. Applicant appeals for review within thirty days of the decision;
ii. Applicant's appeal for review details the grounds for the request based on:

1. Possible technical omissions, real or perceived, in consideration of the original application;
2. Availability of new data not available at the time of original application; or
3. Provision of detailed grounds for applicant's perception of inadequacies of the grounds and technical merits of the decision.

b. Article 56 – Applicant's Right of Appeal

All applicants shall be accorded the right to appeal any decision of the Authority on justifiable grounds of technical or other perceptive nature.

c. Article 57 – Interested Parties Right of Appeal

All interested parties shall be accorded the right to appeal any decision of the Authority on justifiable grounds of technical or other perceptive nature.

VIII. Part 6 – **Emergency Measures and Safeguards**

a. Article 58 – Establishment of Accidental Release GMO Disaster Management/Control Unit

i. Within one year of the enactment of this Bill, an Accidental Release GMO Disaster Management/Control Unit shall be established;
ii. The Accidental Release GMO Disaster Management/Control Unit shall ensure the safe implementation of a GMO disaster management plan in case of an accident; and
iii. Establish mechanisms for the prevention of wide spread genetic pollution and mitigate the risks of such.

b. Article 59 – National GMO Disaster and Risk Management Plan

Within one year of the enactment of this Bill, a draft National GMO Disaster and Risk Management Plan shall be prepared with the support of the requisite technical skills sourced by the NBA.

c. Article 60 – Monitoring and submission of new information

All registered applicants engaged in approved activities relating to the development, release,

transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral vectors, either for research, commercial purposes or human health, plant health and veterinary use, shall be required to submit to the Authority any new information requiring early disclosure within forty-eight hours of the access of that information if the information increases the level of risk beyond what was previously determined.

d. Article 61 – Unintentional introduction into the environment
[to be developed]

e. Article 62 – Importation by sea
[to be developed]

f. Article 63 – Importation by air cargo
[to be developed]

g. Article 64 – Procedures for unloading GMO cargo
[to be developed]

h. Article 65 – Procedures for transport of GMO by road
[to be developed]

i. Article 66 – Storage other than in controlled areas
[to be developed]

j. Article 67 – GMO research containment measures

k. Article 68 – Containment measures for medical GMO applications

l. Article 69 – Duty to Report Threatened releases of GMOs

It shall be the duty of all citizens to report any threat of release of GMOs to the NBA. The NBA shall investigate through its Inspectorate any such reports promptly with the appropriate inter-agency coordination with law enforcement authorities when and where appropriate.

IX. Part 7 – **Pre-Approved Organisms**

a. Article 69 – Register of Pre-Approved GMOs

The NBA shall be required to keep a comprehensive register of all Pre-approved GMOs in a form easily accessible to the public and shall have the power to periodically review information contained therein for additions or deletions to the list as it sees fit on the basis of any new scientific evidence at the time.

b. Article 70 – Public Notification of Pre-Approved GMOs

The NBA shall be required to provide periodic public notifications in two local newspapers, in

both print and electronic forms, on the list of all Pre-approved GMOs. Where relevant such notifications shall be announced by radio and telecast for public guidance to complete information retrieval sources from the print media.

X. Part 7 – **Identification and Documentation of LMOs/GMOs**

a. Article 71 – Register of LMOs/GMOs

The register of LMOs/GMOs maintained by the NBA shall include:

i. Name and identity of the living modified organism/GMO;
ii. Unique identification of the living modified organism/GMO;
iii. Transformation event;
iv. Introduced or Modified Traits;
v. Techniques used for modification;
vi. Description of gene modification;
vii. Vector characteristics of the modification;
viii. Insert or inserts;
ix. Taxonomic name/status of recipient organism or parental organisms;
x. Common name of recipient organism or parental organisms;
xi. Point of collection or acquisition of recipient or parental organisms;
xii. Characteristics of recipient organism or parental organisms related to biosafety;
xiii. Centre(s) of origin of recipient organism or parental organisms;
xiv. Centres of genetic diversity, if known, of recipient organism or parental organisms;
xv. Habitats where the recipient organism or parental organisms may persist or proliferate;
xvi. Taxonomic name/status of donor organism(s);
xvii. Common name of donor organism(s);
xviii. Point of collection or acquisition of donor organism(s);
xix. Characteristics of donor organism(s) related to biosafety;
xx. Intended use of the LMO/GMO in Guyana;
xxi. Receiving environment;
xxii. Summary of risk assessment or environmental review;
xxiii. Detection/Identification method of the LMO/GMO;
xxiv. Evaluation of the likelihood of adverse effects;
xxv. Evaluation of the consequences;
xxvi. Overall risk;
xxvii. Recommendation on level of risk;
xxviii. Actions to address uncertainty regarding the level of risk;
xxix. Availability of detailed risk assessment information; and
xxx. Any other relevant information.

b. Article 72 – Molecular/diagnostic identification of LMOs/GMOs

Where disputation on the accurate determination of the genetically modified trait may arise, the NBA may determine the minimum appropriate tests as recommended by the Biosafety

Advisory Scientific Committee for independent validation or authentication of the identification of the LMO/GMO at the cost of the applicant.

XI. Part 9 – **Biotechnology Research, Innovation and Development (under specific Bill to be drafted)**

a. Article 73 – Biosafety Compliance for Biotechnology Research, Innovation and Development

Notwithstanding all the legal requirements of the Biotechnology Research, Innovation and Development Bill (to be drafted), all activities under the said Bill regarding biosafety and related issues shall comply with this Bill.

XII. Part 10 – **Public Access to Information, Awareness and Participation**

a. Article 74 – Public awareness and participation

The NBA shall maintain regular public awareness and education programmes *via* the local media – newspapers in print, electronic, radio and television. Where appropriate bill boards shall be used. A variety of methods for target groups identified in Schedule 4 to this Bill shall apply.

b. Article 75 – Regional Information sharing

The NBA shall be required to regularly update all national biosafety information as per Schedule 5 to this Bill through its national and regional Biosafety Clearing-house mechanisms, at least quarterly.

c. Article 76 – International information sharing

The NBA shall be required to regularly update all national biosafety information as per Schedule 5 to this Bill through its Convention on Biological Diversity Biosafety Clearing-house Central Portal mechanisms, at least quarterly.

XIII. Part 11 – **Monitoring, Enforcement and Compliance Mechanisms**

a. Article 77 – Inspections at Ports of Entry or Exit

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

b. Article 78 – Inspections of storage facilities

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

c. Article 79 – Inspections of Containment facilities

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

d. Article 80 – Confiscation of GMOs and related products
[to be developed]

e. Article 81 – Offences and Penalties
[to be developed]

f. Article 82 – Limitation Period for Offences
[to be developed]

g. Article 83 – Continuing Offence
[to be developed]

h. Article 84 – Additional Penalties
[to be developed]

i. Article 85 – Civil Claims for Environmental Damage

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

j. Article 86 – Liability of Corporations and Corporate Directors

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

k. Article 87 – Corporate Liability in Case of Bankruptcy

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

l. Article 88 – Liability of Research Institutes and Board Directors

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

m. Article 89 – Liability of Educational Institutions and Board Directors

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

n. Article 90 – Proof of Offence

[to be developed]

o. Article 91 – Procedural aspects
[to be developed]

p. Article 92 – Cessation Orders
[to be developed]

XIV. Part 13 – **Implementation Measures**

a. Article 93 – Regulations
i. Proposal of Regulations

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

ii. Application Fee

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

iii. Pre-Approved GMO registration fee

Upon establishment, the NBA shall within six months seek to develop and establish general guidelines, based on regional and international best-practices.

b. Article 94 – Transitional Provisions
[to be developed]

c. Article 95 – Review of the Act
[to be developed]

XV. Part 14 - **Miscellaneous and Supplementary Requirements**

a. Article 96 – Other Enactments Apply
[to be developed]

b. Article 97 – Delegation of Powers
[to be developed]

XVI. Part 15 – **Schedules**

Schedule 1: Information required in Applications

All Applications for the development, release into the environment, transport and use of GMOs and related products with viable transmissible DNA, RNA, oncogenes and viral

vectors, either for research, commercial purposes or human health, plant health and veterinary use shall include the following:

i. Name and identity of the living modified organism/GMO;
ii. Unique identification of the living modified organism/GMO;
iii. Transformation event;
iv. Introduced or Modified Traits;
v. Techniques used for modification;
vi. Description of gene modification;
vii. Vector characteristics of the modification;
viii. Insert or inserts;
ix. Taxonomic name/status of recipient organism or parental organisms;
x. Common name of recipient organism or parental organisms;
xi. Point of collection or acquisition of recipient or parental organisms;
xii. Characteristics of recipient organism or parental organisms related to biosafety;
xiii. Centre(s) of origin of recipient organism or parental organisms;
xiv. Centres of genetic diversity, if known, of recipient organism or parental organisms;
xv. Habitats where the recipient organism or parental organisms may persist or proliferate;
xvi. Taxonomic name/status of donor organism(s);
xvii. Common name of donor organism(s);
xviii. Point of collection or acquisition of donor organism(s);
xix. Characteristics of donor organism(s) related to biosafety;
xx. Intended use of the LMO/GMO in Guyana;
xxi. Receiving environment;
xxii. Summary of risk assessment or environmental review;
xxiii. Detection/Identification method of the LMO/GMO;
xxiv. Evaluation of the likelihood of adverse effects;
xxv. Evaluation of the consequences;
xxvi. Overall risk;
xxvii. Recommendation on level of risk;
xxviii. Actions to address uncertainty regarding the level of risk;
xxix. Availability of detailed risk assessment information; and
xxx. Any other relevant information.

Schedule 2: Risk Assessment Procedure

All risk assessments of Genetically Modified Organisms shall include the following:

General information

1. The name and address of the applicant.
2. The title of the project.

Information relating to the parental or source organism

3. The full name of the organism: family, genus, species, subspecies, cultivar, pathovar, breed, etc.
4. Information on the reproduction of the organism: mode, generation time and sexual compatibility with other cultivated, cultured or wild species.
5. Information on the survivability of the organism: survival structures, dormancy, etc.
6. Information concerning dissemination of organism: means, extent and factors affecting dissemination.
7. The geographic distribution of the organism.
8. If the species of the organism is not normally grown/cultured in the Caribbean sub-region , describe the natural habitat.
9. Information on any significant interactions of the organism with organisms other than in the ecosystem where it is usually grown/cultured, including toxicity to humans, animals and other organisms.

Information relating to the genetic modification

10. A description of methods used for genetic modification.
11. The nature and source of the vector used.
12. The size, function and donor organism(s) of each DNA sequence intended for insertion.

Information relating to the genetically modified plant

13. A description of the trait(s) and characteristics of the GM organism which have been modified.
14. Information on sequences inserted or deleted: size/structure, copy/number of insert, information on any vector sequences or foreign DNA remaining in the genetically modified organism. The size/function of any deleted regions. Cellular location of insertion (e.g. chromosomal, mitochondria, chloroplast. etc.).
15. Information on the expression of the insert: expression and parts of the organism where expressed.
16. How does the genetically modified organism differ from the recipient organism in mode/rate of reproduction, dissemination, survivability?
17. The genetic stability of the insert.
18. The potential for transfer of genetic material from the genetically modified organism to other organisms.
19. Information on any toxic/harmful effects on human health and the environment arising from the genetic modification.
20. The mechanism of interaction between the genetically modified organism and target organisms.
21. Any potential significant interactions with non-target organisms.
22. A description of detection and identification techniques for the genetically

modified organism.

Information about previous releases of the genetically modified organisms

23. Information relating to the site of release.
24. The location and size of the release site or sites.
25. A description of the release site ecosystem, including climate, flora and fauna.
26. Details of any sexually compatible wild relatives or cultured, reared or cultivated organism present at the release sites.
27. The proximity of the release sites to officially recognized biotopes or protected areas.

Information relating to the release

28. The purpose of the release.
29. The foreseen dates and duration of the release.
30. The method by which the genetically modified organism will be released.
31. The method for preparing and managing the release site, prior to, during, and after the release.
32. The approximate number of genetically modified organisms per square metre or acre to be released.

Information on the control, monitoring, post-release plans and waste treatment plans

33. A description of any precautions to minimize or prevent aerosol, spore, pollen, seed dispersal or other reproductive units from the genetically modified organism.
34. A description of the methods for post-release treatment of the site or sites.
35. A description of post-release treatment methods for genetically modified organism material including wastes.
36. A description of monitoring plans and techniques.
37. A description of any emergency plans.

Information on potential environmental impact of the release of the genetically modified organisms

38. The likelihood of any genetically modified organism becoming more persistent or invasive than recipient organisms.
39. Any selective advantage or disadvantage conferred to other sexually compatible species, which may result from genetic transfer from the genetically modified organism.
40. Potential environmental impact of the interaction between the genetically modified organism and target organisms.
41. Any possible environmental impact resulting from potential interactions with non-target organisms.

Schedule 3: Risk Communication Procedure

It is envisaged the NBA will develop best-practice risk communication with time. However, the basic elements of biosafety risk communication will entail refinement and adaptation of some of the local procedural public engagement mechanism used by the EPA in its EIA process.

The main elements of the biosafety risk communication procedure shall entail recognition of the following:

- There will be the need to identify the specifics and controversial aspects of the perceived biosafety risk, based on the type of GMO application whether for food, feed, contained use, placement on the market or deliberate release into the environment;
- Careful and objective explanation of the risk information;
- Influence of the risk-related behaviour of individuals perceptive of such risk;
- Objective science-based resolution of potential conflicts in risk perception;
- Development of agreeable strategies of emergency risk management plans based on scientific principles on a case-by-case basis; and
- Careful resolution of all ethical implications, if any.

Key stakeholders in the risk communication process shall be:

- The GMO Applicant;
- The National Biosafety Authority;
- The EPA;
- The potential victims of a perceived undesirable biotechnology event;
- Scientists and experts in biotechnology;
- Scientists and experts in biosafety;
- Relevant government agencies;
- Relevant local, government agencies;
- The Guyana Civil Defence Commission;
- The media;
- Civil society;
- Religious groups;
- General public; and
- Interested parties.

Principles of effective risk communication

Some of the key principles of effective risk communication are:

- accepting and involving the public as a partner and stakeholder;
- carefully planning and evaluating the nature and content of the risk communication undertaken so that it is relevant and understandable;
- listening to the public's specific concerns. Trust, credibility, competence, fairness and empathy are often as important to the community as statistics and scientific details. Trust and credibility are very difficult to regain if lost. Experts do not command automatic trust;
- being honest, realistic and open;
- appreciating that intentional communication is often only a minor part of the message actually conveyed. The manner of delivery and its tone may be more important than its content;
- ensuring that information is accurate, consistent between agencies, and not speculative;
- effectively communicating with the media;
- acknowledging the public concerns and the effects on the community; and
- focusing on issues and processes rather than people and behaviours.

(Source: Covello, V.T. and Allen, F. (1988). Seven cardinal rules of risk communication. United States Environmental Protection Agency, Washington.)

Schedule 4: Public Participation Guidelines

Procedure for Public Involvement in Decision-making

1. Following receipt or notification by an applicant and the ensuing administrative processes initiated on the application and subsequent public notification of such application, the Authority shall cause to be published a summary of the basic information in the application on any GMO.

2. The detailed application, except elements of confidentiality identified by the applicant, shall be posted on the National Biosafety Website for public scrutiny.

3. A summary of the any decision, including those on risk assessment, shall be posted for public scrutiny.

4. Following the risk assessment process, the Authority shall be required to make available in suitable form the summary the risk assessment report with relevant key details for public scrutiny.

5. The public shall be given at least fifteen days within any written comments on the risk assessment report would be required.

6. Within fifteen days of the request for public comment on the risk assessment report, the Authority shall hold a public hearing or empanel a citizens' jury session on the risk assessment report and for the solicitation of consensus or majoritarian public opinion.

7. At a public hearing or a citizens' jury session on the risk assessment report, a brief presentation on the GMO application and related risk assessment report shall be made, inclusive of all technical merits and demerits on the basis of the scientific information available at the time.

8. Where there is need to assuage unscientific public perception of an application deemed otherwise biologically and technically safe with low or negligible risk, the Authority shall seek the services of an independent expert to educate and enlighten the public when necessary.

9. A summary of the record of such public hearing or citizens jury on the risk assessment report shall be prepared by the Authority and published in the local newspapers.

10. As far as possible, for the benefit of social cohesion, every effort shall be made by the Authority to ensure any unscientific public perception does not devolve to the detriment of the development of biotechnology and its important role in sustainable development.

Methods to Achieve Biotechnology and Biosafety Public Awareness and Participation

In elaborating on the present good practice processes engaged by the Environmental Protection Agency in public awareness, the NBA shall set in motion an action framework on public awareness, education and participation. The framework shall identify relevant target groups and information and communication mode as follows:

1. ***Use of the Media***
   - Print:
     - newspaper articles,
     - flyers, and
     - posters.
   - Electronic (TV and Radio):

- jingles with popular local lyrics,
- infomercials,
- talk shows,
- websites, and
- email circulars

2. Outreach Programmes

- Seminars;
- Workshops;
- Meetings with interest groups, e.g. farmers;
- Bill boards;
- Trade fairs; and
- Field/outreach trips.

3. Target Groups for general public education and awareness

- Importers;
- Consumers;
- Decision makers;
- Households;
- Schools – quiz, essay competitions, school talks;
- Religious bodies; and
- Professional bodies.

4. Public education on biotechnology and biosafety target groups

- Target Groups:
  - Schools;
  - Educational Institutions;
  - Community Leaders;
  - Communities;
  - Consumers;
  - Producers;
  - Policy Makers;
  - Seed Importers; and
  - Importers – Canned Products.

- Media:
  - Public Meetings;
  - Group Meetings;
  - Community Leaders Meetings;
  - National Democratic Councils, Regional Democratic Councils and Regional Executives;
  - Foot Soldiers;

    - CHW;
    - Agriculture Extension Workers;
    - NDDP – All Personnel;
    - Guyana Consumers Association;
    - TV;
    - Radio;
    - Print; and
    - Internet.

- Workshops/Seminars

- Capacity Building:
    - Technical Training;
    - Trainer of Trainers Training; and
    - Simulation of Biotechnology Process.

- Information must be balanced.

Key Stakeholders in Public Participation Processes for biosafety

Government Agencies:

- Ministry of Agriculture:
    - National Agricultural Research Institute,
    - Guyana Rice Development Board,
    - Pesticides and Toxic Chemicals Control Board,
    - New Guyana Marketing Corporation, and
    - Plant Quarantine.

- Ministry of Fisheries, Crops & Livestock:
    - National Dairy Development Programme, and
    - Guyana Dairy Project (Sophia).

- Ministry of Home Affairs:
    - Guyana Defence Force (Coast Guard, etc.), and
    - Guyana Police Force.

- Ministry of Health:
    - Food & Drugs, and
    - Medical Labs.

- Ministry of Finance:
    - Customs & Excise Dept. and Immigration, and

- Bureau of Statistics.

- Ministry of Legal Affairs:
  - DPP Office.

- Ministry of Education:
  - National Centre for Educational Resource Development, and
  - Schools.

- Ministry of Amerindian Affairs;

- Ministry of Culture, Youth & Sport;

- Ministry of Local Government;

- Ministry of Foreign Affairs;

- Ministry of Foreign Trade & International Cooperation;

- Ministry of Tourism, Industry & Commerce; and

- Bureau of Standards.

Other Agencies:

- Guyana Geology and Mines Commission;
- Guyana Forestry Commission;
- Lands & Surveys Commission;
- Environmental Protection Agency; and
- Guyana Tourism Authority.

Non-Governmental Organisations:

- Iwokrama International Centre for Rain Forest Conservation,
- Conservation International,
- Cattle Farmers Association,
- University of Guyana Centre for the Study of Biological Diversity,
- Religious Bodies,
- Guyana Bar Association,
- Women's Groups, and
- Amerindian Groups (Amerindian Peoples Association, TAAMOG, etc.).

Private Sector:

- Private Sector Commission,

- Guyana Sugar Corporation,
- Guyana Seafoods,
- Guyana Stockfeed,
- Bakeries,
- Breweries,
- Distilleries,
- Tourism and Hospitality Association,
- Mining Companies,
- Guyana Manufacturers Association,
- Georgetown Chambers of Commerce and Industry, and
- Guyana Water Incorporated.

Decision Makers:

- Parliamentary Groups,
- Cabinet Subgroups, and
- Natural Resources, Energy, Mining, Trade.

Research and Education:

- CARDI,
- Guyana School of Agriculture,
- University of Guyana,
- IAST, and
- IDS.

Media:

- Newspapers,
- Radio,
- TV, and
- Internet.

Schedule 5: Information requirements for Notices to the National, Regional and Global

Biosafety Clearing-houses

The basic elements of the national input to the regional BCH shall be:

- Brief introduction/overview of the structure of the national BCH;

- National contacts:
    - National Focal points,
    - National point of contact for receiving notifications regarding unintentional transboundary movements of LMOs/GMOs,

    - BCH national focal points,
    - Competent national authorities, and
    - National databases.

- Laws and regulations:
    - National laws, regulations and guidelines, and
    - Bilateral, regional and multilateral agreements.
- Decisions and declarations pertaining to LMOs/GMOs:
    - Decisions on LMOs/GMOs under Advance Informed Agreement (AIA) procedure,
    - Decisions on LMOs/GMOs for direct use as food or feed, or for processing (LMOs-FFP/GMOs/FFP), and
    - Other decisions and declarations.

- Risk assessments;

- Unique identifications;

- Capacity-building:
    - Capacity-building opportunities,
    - Capacity-building projects and initiatives, and
    - Capacity-building needs and priorities.

- Roster of national experts;

- Other resources:
    - Relevant sites and tools,
    - Bibliographic information,
    - Downloadable files, and
    - Frequently asked questions [where relevant to national specifics].

- Basic information on how to use the national BCH site.

ANNEX 6. ADMINISTRATIVE GUIDELINES

[To be developed as per relevant section of this framework]

ANNEX 7. RISK ASSESSMENT GUIDELINES

[To be developed as per relevant section of this framework]

ANNEX 8. LIST OF SURVEYS AND REPORTS COMPLETED UNDER THE NBF

Survey on the State of General Science and Technology and Related Expertise in Guyana.
Survey on the Existing Uses of Biotechnology, Arrangements for Safe Use and Related Expertise in Guyana.
Review and Assessment of Existing Legislation that may Impact on Modern Biotechnology and Related Expertise in Guyana
Survey on the Existing National, Bilateral and Multi-lateral Capacity Building, Research and Development, and Biotechnology application initiatives in Guyana.
Survey on the Existing National Biosafety Frameworks in countries of the Latin America and Caribbean sub-region.
Review and Assessment of Existing Mechanisms for Harmonization of Biosafety-related Legislation in Guyana.
Survey of the Existence of National or Regional Risk Assessment/Management Capacities and Recommendations for Mechanisms for Harmonization in Countries of Latin America and Caribbean sub-region.
Survey on the Existence, Extent and Impact of Release of LMOs and related Commercial Products in Guyana.
Preparation of a Draft Biotechnology, Biosafety and Biosecurity Policy for Guyana.

ANNEX 9. FEATURE ADDRESS BY THE HONOURABLE PRIME MINISTER

Feature Address by
The Honourable Samuel A.A. Hinds MP, DSc.
Prime Minister of the Republic of Guyana
At the Launching of the National Biosafety Framework Project and 1st National Biosafety Workshop, Georgetown, Guyana. July 28, 2004

On behalf of the Government and people of Guyana, I wish to extend a warm welcome to this significant event. I wish to extend a special welcome to our visiting colleague and friend, the UNEP-GEF Regional Project Coordinator for Latin America and the Caribbean, Dr. Giovanni Ferraiolo, who, I understand, is visiting Guyana for the first time, and to our colleague, the National Project Coordinator from our next-door sisterly neighbour, Suriname.

Mr. Chairman, distinguished members of the head table, Ministers of Government, members of the Diplomatic corps, senior officials, special invitees, members of the National Coordinating Committee on Biosafety, workshop participants, members of the media, ladies and gentlemen:

The Government of Guyana is very pleased to be a partner in this global project on the development of National Biosafety Frameworks involving over 130 countries, and specifically, 14 CARICOM countries. I believe this project stems from the obligations of the Cartagena Protocol on Biosafety – a Protocol that seeks to provide safeguards against unexpected risks of modern biotechnology in mankind's quest to use science and technology for the advancement and improvement of human condition.

Yes, biotechnology has its demonstrably laudable benefits, but we need to be ever conscious and cautious of potential problems to food safety, agriculture, biodiversity, the environment, and health.

My understanding of the importance of the Biosafety Protocol is its genesis in Agenda 21, the blueprint for sustainable development. Agenda 21 articulates the importance of biotechnology in development. Furthermore, the relevant Articles of the UN Convention on Biological Diversity which Guyana ratified in August 1992, barely two months after it was opened for signature in Rio, clearly identify and address biosafety issues, including the need for a Biosafety Protocol.

Guyana values the Convention on Biological Diversity as a very important global compact because of our rich biodiversity heritage and a policy position for sustainable utilization of biological diversity that recognizes the benefits of biotechnology and the need for biosafety guidelines to ensure our beneficence to future generations. In essence, this is *summum bonum* of our environmental ethos, even as enshrined in our Constitution.

As one of the key issues addressed by the Convention on Biological Diversity, the Biosafety Protocol has travelled a very difficult road from the drafting stage, through very difficult negotiations to its finalization and adoption in Montreal on January 29, 2000.

Guyana was one of the 129 countries on one side of the negotiating table with the Miami group of six

countries – Argentina, Australia, Canada, Chile, the USA, and Uruguay – on the other side, precisely because of the issue of potential trade barriers to genetically engineered goods *vis-à-vis* WTO, and the adequacies for addressing safety and risk factors.

Guyana is ever conscious of the trade regime issues of the WTO and the potential adverse impacts some decisions may have on our export commodities such as sugar and rice, and the problems with banana exports already bedevilling some of our sister CARICOM countries. We also realize the growing impact of modern biotechnology on major world commodities such as grains, among other processed commodities, for which we are solely dependent on the world's major grain exporters.

The Cartagena Biosafety Protocol, through its obligatory requirements and the results of this project, would allow us to be better informed about, and better able to regulate, what we import; at least from the perspective of adequate labelling in the short-term. It would also allow us to have advanced informed agreement even in cases where Guyana is just an in-transit location for a genetically modified organism, product, food or feed. Guyana is currently engaged in issues involving the Codex Alimentarius – which, specifically, seeks to provide food safety safeguards in the case of foods derived from genetic engineering/modern biotechnology.

The National Biosafety Framework project, I am advised, will take Guyana and other implementing countries from a zero stage where national biosafety and biotechnology policies, biosafety laws and regulatory regimes are non-existent, to a stage where a draft national biosafety framework document with related draft biosafety legislation would have been prepared. The five key components of the draft biosafety framework to be developed for Guyana being:

- Biosafety policy;
- Regulatory regime including appropriate biosafety laws;
- System to handle requests - which would involve the establishment of administrative, risk assessment and management, and decision-making mechanisms;
- Follow up actions involving – monitoring, inspections and enforcement of biosafety guidelines and laws; and
- Public awareness and participation.

I believe the organizers of this event have elected the latter as an important starting point for sensitization and education of the key stakeholders. I am further advised that a number of targeted awareness programmes are being planned for execution throughout the 18-month life of the project.

The history of the Biosafety Protocol indicates it took four (4) years of meetings and negotiations to arrive at a consensus among the vast majority of countries, except the Miami Group of Six of predominantly grain-exporting countries, leading to the failure to reach agreement in February 1999 at the meeting in Cartagena, Colombia. Further negotiations led to the acceptance of the revised draft Protocol in January 2000 in Montreal.

The Protocol came into force on September 11, 2003. Guyana has signalled its intention to ratify, very shortly, as eight (8) of our CARICOM sisters have done so far. Guyana is happy to have been on the side of precaution during the negotiations and hence the realization of this capacity building project.

We in Guyana place prime value on our biological wealth as demonstrated by the Government and people of Guyana's "gift to the world" through the Iwokrama International Centre for Rainforest Conservation and Development Project, and our partnerships with Conservation International, WWF, GTZ, UNDP, and a number of other like-minded organizations in a variety of sustainable development, conservation and sustainable utilization initiatives.

Though less economically endowed, Guyana has been in the forefront of sustainable development of biodiversity initiatives. As articulated in our *National Development Strategy 2000*, we believe economic development must not be at the expense of destroying the integrity of our environment. We value the role of science and technology as an important ingredient and catalyst in the development process.

Agriculture is vital to the local economy and export sector. To this end, Guyana enacted an Act of Parliament establishing the National Agricultural Research Institute in 1984 with a mandate inclusive of the applications of biotechnology in agriculture. We also established the Institute of Applied Science and Technology at a time when there were few such institutes in developing countries.

The Government and people of Guyana have been taking environmental issues seriously ever since UNCED 1992 Rio summit. We enacted the Environmental Protection Act in 1996, giving birth to the Environmental Protection Agency [EPA], the National Executing Agency for this Biosafety project.

The EPA, despite our perennial human resource inadequacies, has been doing a commendable job to ensure we have all the relevant environmental laws enacted and appropriate environmental guidelines established and enforced. A few months ago I addressed a workshop on the development of our National Protected Areas System. A number of discussions are on-going for funding partnerships.

The National Biosafety Framework project is timely and provides the vital capacity building assistance we need. We are pleased to work in partnership with UNEP and the Global Environment Facility (GEF) to implement this very important project. As a poor country, such partnerships are important to us.

I commend the value and essence of this project particularly to small developing and vulnerable countries such as ours and commend the UNEP-GEF Global Biosafety Project Team in Geneva and Nairobi, Dr. Ferraiolo and his team, for this important task you have engaged on behalf of humanity.

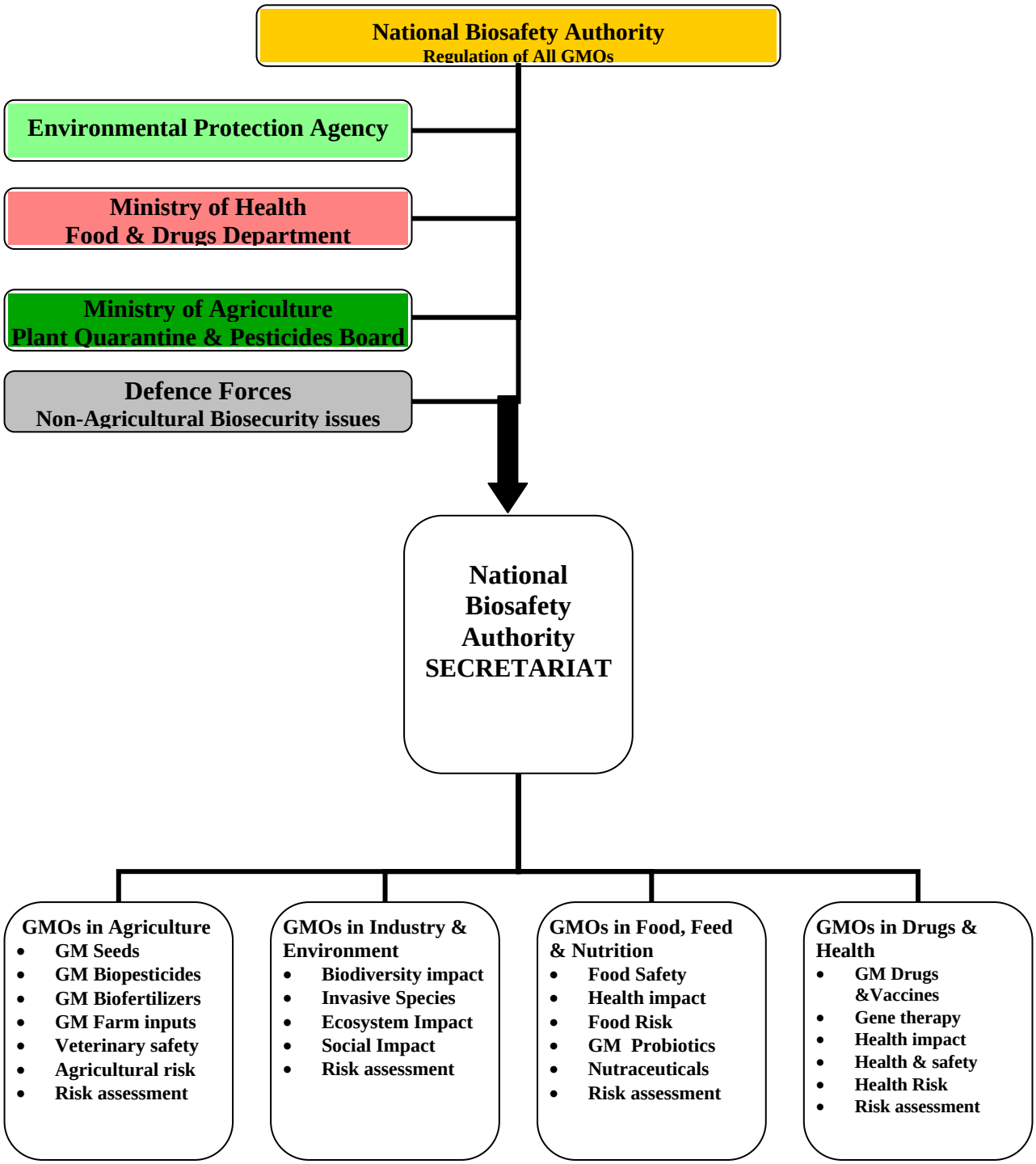
I pledge my Government's support to the Global Project team, the local National Coordinating Committee, and the Project staff in the successful implementation of this important project.

Ladies and Gentlemen: It is my pleasure and honour to declare the National Biosafety Framework Project formally launched and to wish you all very successful and productive deliberations.

Thank you,

Office of the Prime Minister
Georgetown: July 28, 2004

ANNEX 10. THE ROLE OF INSTITUTIONS AND THE FOCUS OF THE NBA SECRETARIAT



ANNEX 11. SAFETY ASSESSMENT OF GM FOOD BEST PRACTICE GUIDE FLOWCHART

(Source: ww